Michigan Technological University

Human Subjects in Research

Institutional Review Board (IRB)
Policy and Procedures

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SECTION I -INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES INVOLVING THE USE OF HUMAN SUBJECTS IN RESEARCH

In order to comply with the DHHS and the Federal Drug Administration (FDA) regulations for the Protection of Human Subjects, Michigan Technological University has established an Institutional Review Board (IRB) to review all research involving the use of human subjects. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human subjects. The IRB, composed of faculty and staff plus community members, is directly responsible to the Executive Director of CIS.

All research involving the use of human subjects conducted by Michigan Tech faculty, staff, or students or sponsored in part or in whole by Michigan Tech must be reviewed and approved prior to the start of the project and then conducted in full compliance with IRB policy and procedures. This includes research conducted in conjunction with classroom assignments as well as a student's dissertation or thesis. It also includes all interviews, questionnaires, surveys, observations, educational tests, and secondary analyses of data previously collected.

This set of guidelines is intended to provide a resource for the preparation and submission of research applications for IRB review. This document includes information on the ethical and legal responsibilities of investigators during the conduct of research involving the use of human subjects.

If at any time you don't know what to do, think that your research might involve special circumstances, have questions, or need additional information, please contact the CIS Office, Lakeshore Center. (906) 487-2902 or email irb@mtu.edu.

A. BACKGROUND AND RESPONSIBILITIES FOR INVESTIGATORS

Michigan Technological University recognizes and affirms the need for academic freedom in the conduct of research, and the value of well-designed, responsible activities which involve human subjects. At the same time, the University recognizes and accepts its responsibility to ensure the protection of any human subject so involved. The use of human subjects in research imposes both ethical and legal responsibilities upon the institution, the principal investigator, and those conducting the research, for ensuring that the rights and welfare of those subjects are adequately protected.

These University policies and procedures have been prepared to help investigators meet individual and institutional obligations with respect to human subjects. They have been developed in accord with federal requirements (DHHS Regulations Title 45 CFR Part 46 and FDA Regulations Title 21 CFR Parts 50 and 56) and the ethical principles embodied in respect for the rights and well being of persons who may be subjects of research. These basic ethical principles include: respect for persons (acknowledging autonomy and protecting those with diminished autonomy), beneficence (doing no harm and maximizing possible benefits while minimizing possible harms), and justice (sharing equitably the burdens and benefits of the research study).

Current law places the burden of liability for negligence and harm directly on the *investigator* and the institution. The IRB procedures are formulated to protect the University, the investigator, and in the case of students, the faculty advisor, from liability through imposition of minimum standards for research, and procedures for careful review of projects. Failure to follow these policies and procedures may cause

individuals to incur personal liability for negligence and harm. Failure to follow these policies and procedures may also cause the University to lose federal funding, prevent individuals from applying for or receiving federal research funds, and prevent the University from engaging in research. In addition, failure to follow these policies and procedures will be viewed by Michigan Tech University as a violation of university policies and procedures and will result in appropriate administrative action.

The Michigan Technological University IRB Procedures involving the Use of Human Subjects in Research has institutional responsibility for use of human subjects in research under the auspices of, or utilizing the students, personnel, or facilities of Michigan Technological University. All projects must be accomplished in accord with these procedures, and all projects covered can be undertaken only after appropriate approval and may be continued only so long as that approval remains in effect. Changes in a project, or continuation of the project following adverse or untoward occurrences during the project, are also subject to review and approval.

It is the responsibility of the investigator to refer his or her project to the IRB whenever humans are used as subjects in research, even if the investigator does not consider the subjects to be "at risk."

B. ETHICAL PRINCIPLES FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

It is the responsibility of the individual investigator to ensure that appropriate ethical principles are adhered to in the conduct of research involving human subjects. The investigator is responsible for the ethical treatment of research subjects by collaborators, assistants, students, or employees who are assisting in the research of the investigator, as well as his or her own behavior.

The University is guided by the ethical principles regarding all research involving human subjects as set forth in the report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The Nuremberg Code, and the World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Humans Subjects. The primary ethical principles which must be considered in all research involving human subjects include:

1. *Maintaining subject autonomy.*

- Participation of human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise, and understandable way. It is the responsibility of the investigator to ensure that subjects understand the principles described and language used in the explanation of the research project. The investigator must also take care to avoid coercing individuals to participate in the study or to remain in the study.

- Adequate standards for informed consent must always be satisfied. The principle of informed consent is derived from the legal and ethical obligation of the investigator to ensure that prospective subjects have sufficient understanding of the benefits and risks of their participation in the study to make an informed decision concerning participation.

2. ***Maintaining the safety of the subject.***

- A paramount responsibility of the investigator is to protect subjects from physical and mental discomfort, harm, or danger. The potential for benefit to others does not justify placing the subjects of the study at risk. A research procedure may not be used if it is likely to cause serious and lasting harm to subjects (e.g., health problems).

- If an investigation utilizes deception, the investigator is required to later explain to the subjects the reasons for this action and to restore the quality of the relationship with the investigator.

- After the data are collected, the investigator should provide subjects with clarification of the nature of the study and remove misconceptions that may have arisen.

- Where research procedures result in undesirable consequences for subjects, the investigator has the responsibility to detect and remove or correct these consequences, including, where relevant, long-term after-effects.

- Where scientific or humane values justify delaying or withholding information, the investigator has a special responsibility to ensure that there are no damaging consequences to subjects.

3. ***Promoting benefit to the subjects and larger community.***

- Wherever possible, the research project should be designed with the intent that the knowledge gained will benefit the subjects and/or a larger community.

- The benefits of the research should be made available to all subjects in the study regardless of their role in the research project.

4. ***Conducting research in a fair and equitable manner.***

- The research should be designed to treat all individuals fairly. The selection of subjects must be based upon fair procedures and not overburden, over-utilize, or unfairly favor or discriminate against any subject pool.

5. ***Honoring commitments made to subjects in a study.***

- The investigator must honor all commitments made to subjects, contributors, or collaborators in a research project. Changes which are made in design must be clearly presented to all individuals involved in the study. It is the responsibility of the investigator to ensure that all parties clearly understand the commitments included in the agreement to participate in or support the study.

- Standards of confidentiality must be respected, particularly in research where this is guaranteed to subjects. If there is a possibility that others may obtain access to any information about subjects which have been gathered during the investigation, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to subjects as part of the procedure for obtaining informed consent.

C. DEFINITION OF RESEARCH

Research is defined as any systematic investigation designed to develop or contribute to generalized knowledge. Research encompasses work which is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the subject involvement even if this work is preliminary to a more extensive study. This definition includes any systematic collection of data from human subjects which occurs in conjunction with classroom projects unless the work is done as a learning exercise for the student and will never be published or presented. Therefore, research leading to theses and dissertations require prior approval by the IRB.

D. CATEGORIES OF RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

All research involving human subjects which is designed to develop or contribute to generalized knowledge through publication or presentation in any medium must receive IRB approval prior to initiation whether it is conducted by faculty, students, or staff. The type of review required depends upon the nature of the research, the subjects, and the risk imposed on the subjects. The three categories of research involving the use of human subjects are described below. In all cases investigators must complete an application. The review procedure and length of time required for review varies for each category.

1. *Research that qualifies for exemption from federal regulations*

An adequate standard of informed consent and confidentiality must be maintained for all research involving human subjects, even that which is exempt from federal regulations. The code of federal regulations (Title 45 CFR Part 46) identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. **When an investigator believes that human research is exempt from federal regulations and when the researcher can demonstrate an adequate standard of informed consent and confidentiality, the investigator must still complete an application for IRB review. Final determination will be made by the CIS Office.**

Research activities in which the **only** involvement of human subjects will be in one or more of the following activities are exempt from federal regulations provided that the information taken from or about these subjects is recorded in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects.

a. When educational research meets the following conditions, it is exempt from federal regulations and does not require parental consent. The investigator and/or the school system may, however, decide that parental consent should be obtained. Whenever possible, child **assent** should be obtained.

(1) All of the research is conducted in established or commonly accepted educational settings, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) If the research involves educational tests (cognitive, diagnostic, aptitude, achievement), this information must be recorded in such a manner that subjects cannot be identified, directly or indirectly or through identifiers linked to the subjects.

(3) The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existing at the study site.

(4) The study procedures involve no increase in the level of risk or discomfort compared to normal, routine educational practices.

(5) The study procedures do not involve sensitive topics (e.g., sex education).

(6) Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.

(7) The school or other institution grants written approval for the research to be conducted.

b. The research involves the use of surveys, interview procedures, or observation of public behavior and is not part of educational research conducted in an established or commonly accepted educational setting described in paragraph "a" above. However, the presence of any one of the following conditions means that the research is **not** exempt from federal regulations and requires an expedited or full board review.

(1) Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.

(2) Any disclosure of subject responses outside the research setting which could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

(3) Survey research dealing with sensitive or highly personal aspects of the subject's behavior, life experiences, or attitudes (e.g., chemical substance use and abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, and detailed health history). The principle determinant of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur.

(4) **Research surveys and/or interviews involving children (subjects under 18 years of age) require an expedited or full board review.**

c. Research involving the use of survey or interview procedure is exempt from federal regulations without exception when the respondents are elected or appointed public officials or candidates for public office and the interview or survey concerns the responsibilities of the office.

d. 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 subjects cannot be identified directly or through identifiers linked to the subjects.

e. Research and demonstration projects which are conducted by or subject to approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(1) public benefit or service programs; or

(2) procedures for obtaining benefits or services under those programs; or

(3) possible changes in or alternatives to those programs or procedures; or

(4) possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies:

(1) if wholesome foods without additives normally contained in the food are consumed, or

(2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an 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.

General characteristics of all exempt research include the following:

- **With very few exceptions, private identifiable information cannot be recorded by the investigator or members of the research team.**
- **Research participants do not sign a consent form.**

2. ***Research that qualifies for expedited IRB review***

Applications which qualify for expedited review are read by a sub-committee of the IRB.

Research activities involving no more than minimal risk and in which the **only involvement of human subjects will be in one or more of the following categories** (carried out through standard methods) may be reviewed by the IRB through the expedited review process. The activities listed below should not be deemed to be of minimal risk simply because they are included on this list.

Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when specific circumstances of the proposed research involve no more than minimal risk to subjects. In addition, previously approved (within one year or less) research with only minor changes qualifies for expedited review. The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no more than minimal.

Applicants are reminded that the requirements for informed consent apply regardless of the type of Review--expedited or full board.

a. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.

(1) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(2) Research on medical devices for which an investigational device exemption application is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts must not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or from other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings in a non-disfiguring manner; deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction, permanent teeth if patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva either collected in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

d. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis) although some research in this category may be exempt.

f. Collection of data from voice, video, digital, or image recording made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt).

3. ***Research requiring full IRB review***

All research involving the deception of subjects (the researcher deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study); sensitive behavioral research (such as research relating to illegal activity or sexual activity); or research involving pregnant women, prisoners, mentally incompetent people; or research harmful to the subjects automatically requires review by the full IRB. Additionally, if a proposal is submitted as an expedited proposal but does not receive approval at the expedited level, it will be reviewed at the full IRB level. This may occur if information is omitted or procedures are unclear. In such cases, expedited reviewers are unable to evaluate risks to subjects, and must request a full board review. Such action often delays onset of the project.

All other research involving the use of human subjects requires full review by the IRB unless it qualifies for exemption from federal regulations or expedited IRB review as described above.

4. ***Student Research***

Student research follows the same guidelines as all other research. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project requires IRB approval. If an instructor determines that a research project is assigned for the purpose of producing generalized knowledge which may be presented or published, that it may involve risks to the subjects, or that it may be supported by grant funds, the student investigator must comply with the procedures contained in this document. IRB approval must be received **prior** to the student initiating the research. If there is any doubt as to whether the project should be reviewed by the IRB, contact the CIS Office for assistance.

Class assignments which are intended to provide research experience for the student and not generalized results are not governed by the procedures contained in this document. However, this does not relieve the student and instructor of the obligation for ethical use of human subjects. Consequently, the research should adhere to ethical standards and use informed consent and child assent procedures when appropriate. An application filed with the IRB for information purposes is strongly encouraged

5. ***Research Conducted Cooperatively with Another Institution***

In the conduct of research involving more than one institution, **each** institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations. Joint or cooperative IRB review of such studies which is intended to eliminate the duplication of each institution responsible for the same research project is allowed.

Generally, in a cooperative research review agreement, one institution agrees to delegate the responsibility for initial and continuing review or review of a portion of the research activity to another IRB. In turn, the other institution and IRB agree to assume responsibility for initial and continuing review in accordance with the agreement. The institution delegating the responsibility for review must understand that it is agreeing to abide by the reviewing IRB's decisions. The delegating institution remains responsible for insuring that the research conducted within its own institution is in full accordance with the determinations of the IRB at the institution providing the review.

The agreement for IRB review of cooperative research must be documented in writing with copies to be furnished to all parties to the agreement, and those responsible for ensuring compliance with the regulations and the IRB's determinations. Investigators should seek IRB counsel prior to engaging in cooperative research involving the use of human subjects.

6. Research Conducted in Foreign Countries

Research which is conducted in a foreign country should take into consideration the culture and local customs of that country when dealing with human subjects. In some cases, the usual IRB requirements may be waived, while in others, the procedures to protect human subjects in that country may exceed the policies and procedures set forth in this document. The disclosure of HIV positive serostatus may be more or less appropriate in different cultures or countries. It is best to discuss research projects conducted in foreign countries which involve the use of humans as subjects with the IRB during the planning phase of the project.

E. IRBNet SUBMISSION INFORMATION

IRBNet is a web based document management system. ALL research conducted by Michigan Tech faculty, students, or staff involving **humans** MUST be submitted and stored using IRBNet.

IRBNet is the ONLY accepted submission method for the following:

- All NEW applications
- Requests for Exemption
- Requests for changes during the approval period
- Requests for renewals, with or without modifications

- Requests for closure when a project is done

Note: If a Study Package has been submitted to OR determined by our office that it needs to be reviewed by more than one committee; you must receive approval from ALL appropriate Review Committee(s) via IRBNet BEFORE research activities begin. *This includes all exempt protocols.*

SECTION II -INSTRUCTIONS FOR APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH or CLASSROOM SITUATIONS

Prior to submitting an application, you are encouraged to read and understand the IRB Procedures Involving the Use of Human Subjects in Research. Required CITI training needs to be completed prior to application submission. A description of how to prepare an application follows.

IT IS ESSENTIAL THAT YOU PROVIDE ADEQUATE TIME FOR YOUR PROPOSAL TO BE REVIEWED TO ASSURE ADEQUATE TIME FOR POTENTIAL REVISIONS. RESEARCHERS ARE ENCOURAGED TO SUBMIT THEIR PROPOSALS TO ALLOW FOR APPROVAL DETERMINATION TO BE MADE TWO (2) WEEKS PRIOR TO THEIR ANTICIPATED START DATE. THE ACTUAL TIMELINE MAY VARY DEPENDING ON THE IRB MEETING SCHEDULE IF FULL BOARD REVIEW IS REQUIRED. CALL THE CIS OFFICE IF YOU HAVE ANY QUESTIONS.

A. Application Instructions

The following instructions are provided as a guide to help investigators prepare a complete application.

Prepare the research protocol and consent materials for committee review according to the following guidelines. Applications should be concise. The application should include required information but not information which is irrelevant for IRB review. Copies of consent forms, questionnaires, or other instruments must be included.

1. Application Cover Sheet
    a. Each NEW study package submitted must contain the required **Application Coversheet,** it is NOT an IRBNet library document. It is a wizard document contained within the individual study package. You will be guided through a few pages answering background questions about your study until you reach the final page where you will click on Save and Exit. This Application Coversheet will then automatically upload with your other study package documents. Be sure you review the final document prior to submission for accuracy. This form will provide our office with valuable information about the project. Be sure you review the final document prior to submission for accuracy, and that you have read, understand, and agree with the assurance statement contained within the Application Coversheet.

       If students are involved in a project, s/he should be listed as a co- investigator / other personnel and explain their role in the field provided

2. Protocol - include the following research procedures:

- Describe the purpose, objectives, design, and site of the research in straightforward nontechnical language.

- Include where the research will be conducted.

- State who will conduct the research and how many investigators will be involved.
- Describe the training procedure for the researcher and/or persons assisting in the research. This should include information which demonstrates the researcher's ability to carry out the responsibilities in the project (such as clinical training and/or certification, course work, etc.).
- Describe the data gathering instruments that will be used.
- Describe the procedures for videotape or audiotape collection and coding, if applicable.
- State the frequency and duration of all treatment procedures.
- State the time frame for participation in the project.

3. Instrumentation, addendums, or additional documents

- Attach a copy of all recruitment flyers, questionnaires, interview schedules, or data collection instruments. This would include screen shots of the first page for on-line surveys.
- Describe any apparatus used for data collection.

4. Characteristics of subjects

- Describe the subject population in terms of the number of subjects, age or age range, gender, ethnic background, and/or health status.
- Provide a rationale for the use of special classes of subjects (children, pregnant women, fetuses, mentally retarded, mentally disabled, prisoners, or other vulnerable groups).
- If data collection is to be done in a classroom setting, explain what students who do not participate in the research project will be doing.
- Attach a letter giving approval from any agencies that will be involved with the data collection.
- Identify the source of the potential subject pool. If this source is a publicly available list, please indicate so.
- Describe how the subjects will be selected. Is participation voluntary? Is the possibility of coercion minimized? Are compensation or rewards explained? (Attach advertisements or flyers, cover letters used in survey research, or scripts used in solicitation procedures.)
- Provide assurance that there will be no unauthorized access to private or confidential information in the securing of the pool of potential subjects. Document that you have the right to access the information.
- Describe the criteria and procedure used to select research participants from the pool of all possible participants.
    - If selection is to be accomplished on the basis of document review, provide assurance that

the researcher will not have unauthorized access to private or confidential information.

- If selection is to be accomplished on the basis of primary data collection, this must be made clear to the subjects during the initial consent process. Include appropriate debriefing information for individuals removed from the research and an additional consent form for those remaining as subjects in the research project.

5. Benefits

- Describe the benefits to the subjects or larger community.
- State clearly the importance of expected knowledge to be gained from this research project.

6. Risks and protection of subjects

- Describe the nature and likelihood of possible risks or discomfort to the subject including physical risk (e.g., pain, bruising, infection, soreness, injury), psychological risk (e.g., stress, feelings of guilt or discomfort), social risk (invasion of privacy, loss of community standing), legal risk (e.g., criminal prosecution), and economic risk (e.g., loss of employment, loss of potential monetary gain).
- Describe any potential reactive effects of the instrumentation as well as the treatment.
- Describe how confidentiality will be maintained. Have the risks of a breach of confidentiality been considered? What precautions have been taken to minimize these risks?
- Describe the final disposition of materials used to gather data (e.g., questionnaires, inventories, videotapes, audiotapes), if necessary.
- Describe measures ensuring professional intervention in the event of adverse effects to the subjects.
- Address issues of privacy and potential coercion for research involving vulnerable subjects.

7. Informed consent and child assent

- Describe the method for obtaining informed consent.

Write the consent form (and written project description for subjects if separate from the consent form) in readable, easy to understand lay terms. Consent forms are typically not required for anonymous surveys. However, surveys should include a cover letter that describes the nature and purpose of the research, the procedures for returning the survey, the amount of time required to complete the survey, any foreseeable risks and discomforts of completing the survey, the foreseeable benefits, the likelihood subjects could be identified and the extent to which date will be held confidential, the voluntary nature of participation, and the investigator's (**and for student projects, the faculty advisor's**) name and telephone number(s).

Type the first page of the consent form on Michigan Tech letterhead or type "Michigan Technological University" at the top of the form.

The consent form should include:

a. The nature and purpose of the research. (If applicable, students should state that the research is being conducted in fulfillment of degree requirements at Michigan Tech University).

b. The procedures to be followed.

c. The time and duration of subjects' participation.

d. The foreseeable discomforts or risks.

e. For cases involving more than minimal risk, the compensation and the availability of medical treatment if injury should occur.

f. The foreseeable benefits.

g. The extent to which data will be held confidential.

h. The voluntary nature of participation and withdrawal.

i. The investigator's (and for student projects, the faculty advisor's) name and telephone number(s).

j. The IRB administrator's contact information.

k. Provide space for the subject's signature and a place for date.

- Write child assent forms in language that is appropriate to the population for which it is designed.
- State clearly that each subject will receive a copy of the consent/assent form.
- Attach consent and child assent materials which you will use.

8. Confidentiality:

- Describe the precautions that will be taken to ensure the privacy of subjects and confidentiality of information. Be explicit if the data are sensitive. Include:

  a. How and where any information which could identify subjects will be kept.

  b. Who has access to information which could identify subjects?

  c. How long any information which could identify subjects will be kept.

  d. The plans for disposition of information which could identify subjects, if appropriate.

- If you include any or all of the above information under Risks and Protection of Subjects, do not repeat that information, but state that the information is included in that section.
- If the subjects have been assured anonymity, describe coding procedures which ensure that:

(a) no individual identifier is used in any way, or (b) an individual identifier cannot be linked to an individual subject outside of the research database. If the project involves subjects who are anonymous, confidentiality should not be addressed since the investigator is not privy to information related to subjects.

- If the data are collected in an electronic format (audiotape or videotape), clearly specify the following in addition to the information requested above:

    a. If transcriptions will be made of the tapes, indicate who will make the transcriptions. Describe the procedures that will be instituted during transcriptions to remove identifying information. Who will have access to the transcriptions?

    b. Describe any plans to use the taped information for purposes other than this research.

- If the data are collected by observation of behavior without explicit agreement of the subjects, clearly specify the following:

    (a) the subjects have no reasonable expectation that their behavior is private, and (b) the data will have either no individual codes or coding will be unrelated to the individual under observation.

B. Continuing Review and Submission of the Annual Update

Expedited and full board applications are approved for a maximum of one year. For projects which continue beyond one year, a Renewal Request form must be submitted. It is the responsibility of the investigator to submit an annual update with the first update due 12 months following the date the application was approved. If the IRB determines that a project requires review more often than annually, the investigator will be notified.

C. End of Project Report, Storage and Disposal of IRB Records

For expedited or full board projects, researchers are required to submit an Completion Form at the conclusion of the data collection phase of their research (this is not required for exempt proposals). If the data collection phase is not complete within 12 months following project approval, it is the responsibility of the researcher to submit to the IRB a Renewal Request form (see B above).

IRB files pertaining to approved applications are maintained for a period of three years beyond the last approved end-date and then archived. Files regarding denied applications are kept for a period of three years following the date of application and then archived. The IRB will maintain a list of approved and unapproved projects (i.e., the name of the principal researcher and the title of the study).

D. Reporting Changes in a Research Protocol

Any change in a protocol which affects the human subjects must be approved by the IRB prior to implementation except where an immediate change is necessary to eliminate a hazard to the subjects. Investigators should submit a request for change in protocol to the IRB. If the protocol change requires changes in the consent forms, attach the new consent forms to the request for change. Minor changes will be reviewed by an expedited review procedure.

E. Submission of a Report of Injury

If a subject suffers an injury during research, the investigator must take immediate action to assist the subject and notify the IRB of the injury within 48 hours.

F. Reporting Non-Compliance with IRB Policies and Procedures

Any incident of non-compliance with IRB policies and procedures should be reported immediately to the IRB (Lakeshore Center).

Section III -Research Involving the use of Special Groups

The federal government has identified several special populations which are considered to be vulnerable. These populations include: children, fetuses, pregnant women, human in vitro fertilizations, and prisoners. Because of their special classification, research involving any of these populations must follow all requirements listed in this section **in addition** to the policies and procedures contained in Section I of this document.

The information provided below is a summary of federal regulations. A copy of the federal regulations governing research involving any of these special groups may be obtained from the Compliance, Integrity and Safety Office, 317 Administration Building. The investigator is responsible for following **all** of the applicable guidelines contained in 45 CFR 46.

A. Research Involving Prisoners as Subjects

Due to their incarceration, prisoners may be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether to participate as subjects in research. Therefore, special safeguards are provided for their protection.

- A majority of the IRB should not have any involvement with the prison or facility from which the subjects will be selected. In addition, at least one member of the IRB must be a prisoner or a prisoner representative with appropriate experience and background.

- When designing research involving prisoners, the researcher should take care to insure that:

    a. Any possible advantages accruing to the prisoners are not of such magnitude that their ability to weigh the risks of the research is impaired.

    b. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or other prisoners.

    c. Unless waived in writing by the IRB, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the research project.

    d. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research project in making decisions regarding parole, and each prisoner is clearly informed of this in advance.

e. Where follow-up procedures are required as a part of the research project, adequate provision must be made taking into account the varying lengths of individual prisoners' sentences.

- Prisoners may be used in research conducted for the following purposes only: research studying the possible causes, effects, and processes of incarceration, criminal behavior, prisoners as incarcerated persons, and prisons as institutional structures provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

- Prisoners may be used as subjects in the following types of studies only after approval by the Secretary of DHHS: research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the prisoner; and studies which require the assignment of prisoners to control groups which may not benefit from the research.

B. RESEARCH INVOLVING FETUSES, PREGNANT WOMEN, AND HUMAN IN VITRO FERTILIZATION

Special care is taken to protect this group of subjects in research. Absolutely no research involving human in vitro fertilization may be undertaken until the application has been approved by the Ethical Advisory Board of the DHHS.

- The following general limitations apply to all research projects involving fetuses and pregnant women.

  a. No research may take place unless appropriate studies on animals and nonpregnant women have been completed except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

  b. Individuals engaged in the activity will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy and in determining the viability of the fetus at the termination of the pregnancy.

  c. No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

  d. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

  e. Consent must be obtained from the mother and father unless the purpose of the activity is to meet the health needs of the mother only in which case the father's consent is not needed or if the father's identity or whereabouts cannot be ascertained, he is not reasonably available, or the pregnancy resulted from rape.

- Pregnant women may be involved as research subjects only when the risk to the fetus is minimal or when the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs.

- No fetus in utero may be involved as a subject in research unless the purpose of the research is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

- Until it has been ascertained whether a fetus ex utero is viable, it may not be used as a subject in research unless there will be no added risk to the fetus and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

- No nonviable fetus may be involved as a subject unless vital functions will not be artificially maintained, experimental activities which would terminate the heartbeat or respiration of the fetus will not be employed, or the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

- Activities involving a dead fetus, macerated fetal material, or cells, tissues, or organs excised from a dead fetus shall be conducted only in accordance with State or local laws.

C. RESEARCH INVOLVING CHILDREN

Children are considered to be a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and, therefore, considerations are required by the federal regulations for research involving children except that which is conducted in an educational setting as described in Section I of this document. Note that, whenever feasible, appropriate studies should be conducted on animals, adults, and older children before young children are involved as research subjects.

The IRB is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children, as well as the permission of parents or legal guardians. The IRB's policy with respect to obtaining consent from the parents or legal guardians and assent from minors is specified below:

- In most cases, parental consent must be obtained if the research involves minor persons (under the age of 18). A written consent form must be used to document informed consent. Parents must sign the consent form unless this requirement is waived by the IRB. (The requirement for parental consent may be inappropriate in some cases, such as research on child abuse.)

- Unless the requirement is waived by the IRB, documentation of assent is also required for all children. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. The form should include a simplified version of the elements of informed consent which were described in the general instructions. Note that the child should be given an explanation, at a level appropriate to the child's age, maturity, and condition of the procedures to be used, their meaning to the child in terms of discomfort, risk, and inconvenience, and the general purpose of the research. If the child's developmental ability precludes obtaining written assent, documented oral assent is sufficient.

D. RESEARCH INVOLVING MENTALLY INCOMPETENT SUBJECTS

A mentally incompetent prospective subject is a person who has either been adjudicated to lack the capacity to give informed consent or is judged by the investigator to lack that capacity. A prospective subject who lacks the capacity to give informed consent cannot participate as subject in research unless proxy consent is obtained by the subject's legally authorized representative. Whenever possible, subject assent must also be obtained. Information in greater detail and assistance developing forms for consent, assent, and durable power of attorney may be requested from the IRB.

E. RESEARCH INVOLVING PREVIOUSLY COLLECTED HEALTH-RELATED DATA

The HIPAA guidelines require that research involving the use of health-related data must follow certain guidelines in addition to those required by the IRB. Although HIPAA recognizes that health-related information may never be made truly anonymous, the risk of re-identification of an individual is greatly decreased by removing certain elements from research data. Data lacking these elements is said to be de-identified and is excluded from the rules governing use of Protected Health Information.

HIPAA "Safe Harbor" De-Identification of Medical Record Information requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de- identified: (for more information regarding HIPAA guidelines in research see: http://apps.research.uci.edu/tutorial.

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:
   a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
   b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers
16. Full face photographic images and any comparable images
17. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

SECTION IV -INFORMED CONSENT GUIDELINES AND MODEL FORMS FOR RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

A. INFORMED CONSENT GUIDELINES

TEMPLATES AND SAMPLE FORMS MAY BE FOUND IN THE IRBNet LIBRARY.

The investigator has a legal and an ethical obligation to ensure that the prospective subject sufficiently comprehends the elements of the informed consent materials and is able to make an enlightened decision to participate in the research project. Informed consent should be obtained by utilizing a simple but complete consent form written at the appropriate educational level. The consent form, however, does not by itself constitute informed consent. Rather, the informed consent form should serve as a guide by which the investigator carefully, patiently, and simply explains the elements of consent to the prospective subject. The investigator should periodically assess the prospective subject's comprehension by asking appropriate questions. After the investigator has determined that the prospective subject has sufficient knowledge and comprehension of each element of consent, the subject should voluntarily sign and date the consent form in the presence of the investigator. A witness and a short form written consent are required if the elements of informed consent must be presented orally to subjects rather than in writing. Consent for treatment is not the same as consent to participate in research. A subject may desire treatment without desiring to participate in a research study. The guidelines in this document deal with consent to participate as a research subject only.

The legal obligation to secure informed consent is founded on the principles outlined in DHHS Regulations 45 CFR 46.116, 117; Principle I of the Nuremberg Code, and Principles 9, 10, 11 of the Declaration of Helsinki. Subjects must be informed of all features of the research that may influence their decision to participate. If the research creates any risks of physical or mental discomfort, harm, or danger, the investigator is required to inform the subject of that fact and to secure consent before proceeding. If the subject is to be videotaped, photographed, or audio taped, that must be disclosed.

An explanation of who will maintain custody of the data, who will have access to them, and how they will be used must be provided. All aspects of the research about which the subjects inquire must be explained to their satisfaction. The subject must be given a copy of the informed consent document and must be provided adequate opportunity to read it before signing. If the elements of informed consent will be presented to the subject orally, there must be a witness to this presentation who signs a summary statement of both the research project and the material presented to the subject orally.

The following elements should be included in any informed consent decision:

1. Materials must be written in language that the subject can understand, including simple or lay explanations for apparatus and procedures to be employed. Ordinary language should replace technical terms (e.g., upper extremities should be referred to as arms, hematoma as a bruise, venipuncture as taking blood from the arm with a needle, the amount of blood to be withdrawn should be described in terms of teaspoons rather than milliliters).

2. Describe the nature and purpose of the research. If applicable, students should state that the research is being conducted in fulfillment of degree requirements at Michigan Technological University.

3. Estimate the duration of the subjects' participation.

4. Describe the procedures to be followed, including how any audio or visual recordings will be used. Identify any procedures which are experimental.

5. For research involving more than minimal risk, provide an explanation as to whether any compensations or medical treatments are available if injury occurs, and, if so, what they consist of, where they may be obtained, and where additional information may be obtained.

6. Discuss any foreseeable discomforts or risks which may be expected from the research.

7. Discuss any foreseeable benefits to the subject or others which reasonably may be anticipated.

8. Describe the extent to which confidentiality of records identifying the subject will be maintained. If there is a possibility that others may obtain access to any information about the subject gathered during the research, this must be made known to subjects along with the plans for protecting confidentiality.

9. Include a statement that participation is voluntary and the subject is free to withdraw at any time without risk of penalty or loss of benefits to which the subject is otherwise entitled.

10. Include an offer to answer any questions about the procedures. Provide the name and phone number(s) of the investigator(s) (or in the case of student investigators, the faculty advisor) who may be contacted for further information. Provide the name and phone number of the IRB Administrator who may be contacted for further information.

11. In no case may the person's consent be based on an agreement, written or oral, through which the subject is made to waive, or appear to waive, any legal rights, or to release the University, its agents, or the investigator, from liability for negligence.

12. If subjects are minors (under 18 years of age) a parent or guardian must sign the Informed Consent Form.

B. Assent Procedures for Research Subjects Who are Children

Legally, children (those under the age of 18) cannot give consent on their own behalf. The consent of their parent(s) or a legal guardian is, therefore, required before they can participate in research projects as a subject. In addition to obtaining parental/legal guardian consent, the investigator must also solicit assent of children who participate in the research as subjects. Assent forms for children must contain simple language written at the appropriate educational level of the youngest prospective subject. In most circumstances, a child's deliberate objection should be regarded as a veto to involvement in the research. However, parents or guardians may, with IRB approval, override a minor's objections to interventions that hold the prospect of direct benefit to the child.

C. Preparing Consent/Assent Forms

A prospective subject's ability to understand the elements of informed consent is a function of intelligence, education, maturity, and language skills. It is, therefore, necessary to adapt the language level of the consent form to fit the subject's capabilities. The informed consent form must be written in simple enough language so that it is readily understood by the least educated, least sophisticated of the subjects to be utilized. The

informed consent form should be lengthy enough to explain consent factors adequately, but not so lengthy or detailed as to lose the attention of the subject or to cause confusion.

The informed consent form should be written in the second person (e.g., you are invited to participate) until the paragraph preceding the subject signature line. That paragraph should be written in the first person as follows:

My signature below indicates that I have voluntarily decided to participate in this research project as a subject and that I have read and understand the information provided above.

If the consent form is longer than one page, a blank for the subject to initial should be placed at the bottom of all pages except the page containing the subject's signature. The signature of a witness is required for all research studies involving more than minimal risk. The witness should be someone who is not involved in the study. The investigator should write an assurance statement such as:

In my judgment, the subject is voluntarily and knowingly giving informed consent to participate in this research study.

Then, sign and date the consent form in the presence of the subject and the witness (if required).

If the consent form will be used for parents or other legally authorized representatives consenting on behalf of a minor or other legally incompetent subject, the consent form should be written in a style that reflects the fact that it is the minor or other subject who is the participant and the consenter is agreeing to allow said subject to participate in the study. The informed consent form must not contain any language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

Signed copies of informed consent and child assent forms must be maintained by the principal investigator and be stored in a secure manner. The usual retention period is three years beyond the termination of the study. If the investigator resigns from the University before the end of the designated period, the informed consent forms must be maintained by the department of record.

SECTION V -GUIDELINES FOR IRB REVIEW

The following information is provided to assist the IRB in its review process. It is included here as it may be helpful to investigators in preparing application materials for review.

In order to approve a research project involving human subjects, the IRB must assure itself of the following:

1) the prospective subject population is appropriate in terms of characteristics and number,

2) the recruitment of subjects is free of coercion,

3) the experimental design of the study is sound,

4) any risks associated with the research project are minimized to the greatest extent possible,

5) the potential benefits are maximized to the greatest extent possible,

6) the risks to the subject are outweighed or balanced by the potential benefits,

7) the level of subject compensation (if any) is fair and non-coercive,

8) the degree to which confidentiality is maintained is acceptable,

9) the method used to obtain informed consent is ethically and legally acceptable, and

10) the investigator has the appropriate qualifications, experience and facilities to conduct the research.

The IRB review process is not particularly concerned with the nature of a research topic, as long as the rights and welfare of the subjects are adequately protected and the protocol will be conducted in full compliance with DHHS regulations.

1. Review of the Prospective Subject Population

The prospective subject population must be appropriate with respect to the nature and goals of the research. In addition, the investigator should be guided by the principles which lead to an equitable selection of subjects with regard to the potential risks and benefits of the research. The IRB, therefore, will examine carefully the characteristics of the subject population. Factors such as the required number of subjects, age range, sex, ethnic background, and health status will be considered. The utilization of any vulnerable classes of subjects such as pregnant women, fetuses, prisoners, children, and mentally incompetent persons must be clearly justified. Although the use of vulnerable persons as subjects is not prohibited by any regulations or ethical codes, justification for involving vulnerable persons in research generally becomes more difficult as the degree of risk and vulnerability increases.

Naturally, there are exceptions to the principle of "equitable selection of subjects." For instance, research involving the social consequences of a disease to which only one ethnic or racial group is susceptible would not require the application of this principle. Two examples are sickle cell anemia in the black population and Tay-Sachs Disease which affects Jewish people.

2. Review of Method(s) of Subject Recruitment

The IRB will review the method of prospective subject identification and recruitment in order to be assured it is ethically and legally acceptable. Advertisements used to recruit subjects are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by the IRB.

3. Review of Experimental Design

The IRB will review the experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits to the subjects are maximized by using procedures consistent with sound research design.

The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be fully justified. In general, deception is not acceptable if in the judgment of the IRB the subject would have declined to participate had they been informed of the true purpose of the research. Studies

which use deception and/or the withholding of information as part of their experimental design must include a post-study debriefing unless a waiver is granted by the IRB.

4. Review of the Potential Risks

A risk is a potential harm (injury) associated with the research that a reasonable person, in what the investigator knows or should know to be the subject's position, would be likely to consider significant in deciding whether or not to participate in the research. The concept of risk includes discomfort, burden, or inconvenience a subject may experience as a result of the research procedures. Underlying the consideration of risk is the implicit moral guideline that all investigators have a duty not to harm their subjects and must minimize potential risk to the greatest extent possible.

The five major types of risks are: a) physical risk (e.g., pain, bruising and infection associated with venipuncture, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test); b) psychological risk (e.g., stress associated with psychological testing, feelings of guilt or discomfort precipitated by a sensitive survey); c) social risk (e.g., invasion of privacy, loss of community standing); d) legal risk (e.g., criminal prosecution or revocation of parole); and e) economic risk (e.g., loss of employment, loss of potential monetary gain).

Both immediate and latent (delayed) risks of any procedure involving human subjects will be reviewed by the IRB. In addition, the estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable subjects may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the subject. Victims of child abuse or assault, for example, may be at increased risk in sociological or psychological studies. Children, the elderly, prisoners, the mentally incompetent, and various ethnic groups may incur an increased level of risk in certain kinds of research projects.

Risk can also be classified as less than minimal, minimal, and greater than minimal. Federal regulations (45 CFR 46.102g) define minimal risk as "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." The term "minimal risk" is used as a base or standard by which the risk associated with research is judged.

Examples of "less than minimal risk" procedures include collection of urine, collection of sweat, weighing, pulse measurement, blood pressure measurement, voice recordings, skin fold body composition measurements, and any standard psychological testing with no stress. In actuality, most less than minimal risk procedures are interventions that usually (but not always) have no known associated risk but which are not considered exempt from federal regulations under 45 CFR 46.101b and, therefore, must be reviewed by the IRB using the expedited or full board method. For example, if an investigator were to take one blood pressure measurement using a sphygmomanometer, this would clearly be a "no known risk" procedure. If, however, the investigator's protocol requires monitoring of the subject's blood pressure every thirty minutes during a five hour written exam given for Board certification, the associated risk would be at least "less than minimal" as opposed to "no known risk." This is because of the inconvenience and discomfort associated with the multiple interventions. Since risk is such a relative concept, the IRB classification system does not distinguish between "no known risk" and "less than minimal risk" research except for the purpose of risk disclosure on the consent form.

5. Review of Potential Benefits

A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to the subject directly (e.g., acquisition by the subject of knowledge considered of value) and those that accrue to society (e.g., additions to the knowledge base). The IRB will review the anticipated benefits to both the subject and to others. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Therefore, an underlying moral notion of "beneficence" should guide the investigator.

Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the subject may consider financial compensation a desirable outcome, this fact will not be used in the risk/benefit analysis.

6. Risk/Benefit Analysis

Once the potential risks and benefits are identified, an ethical review of research requires an examination of the relationship of the risks to the benefits. Risks and benefits cannot be considered parallel constructs and, therefore, no formula is applicable. The various ethical codes and regulations, however, require a favorable balance between harm and benefit. To assist the investigator and the IRB in assessing the risk/benefit relationship the following principles are provided.

a. In non-therapeutic research the potential risk to the subject must be outweighed, or balanced, by the potential benefit to the subject and/or by the potential benefit to society.

b. In research where a standard therapy not part of the research protocol is employed solely for the benefit of the subject along with additional procedures performed solely for research purposes, the anticipated benefits of the therapy must not be used to justify exposing subjects to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Conversely, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.

7. Review of Subject Compensation

The IRB will review the amount of compensation (monetary as well as other forms) in order to be assured that it is not coercive and is equitable in distribution. Michigan Tech must satisfy certain IRS reporting obligations when making compensation payments to human subjects. These payments to any (1) individual that exceed a $600 threshold during a calendar year are subject to certain IRS reporting regulations. Refer to the pdf document found on our web site under Resources labeled Procedure for Compensation to Human Subject Participants at this location:
http://www.mtu.edu/research/administration/integrity-compliance/review-boards/human-subjects/

8. Review of Confidentiality

The IRB will review the methods to be used to preserve confidentiality. If research data with subject identifiers will be made available to persons other than the listed investigators, the IRB will review the justification for sharing these data and determine acceptability.

9. Review of Informed Consent

Although there are federal regulations requiring the subject or the subject's legally authorized representative to give consent prior to the subject's participation in an experiment, the principal reason for informing subjects about an experiment is that they have a moral right to know what is to be done to them and what risk this entails before they give their consent. Human beings are considered autonomous and the requirement of informed consent is designed to uphold the ethical principle of "respect for persons." The use of human subjects is a privilege granted to the experimenter, rather than a right. An experiment is something that is done to the subject either primarily or solely for the purpose of advancing knowledge. Indeed, in non-therapeutic research, the subject seldom receives any benefit.

In order for consent to be ethically and legally valid it must meet the requirements stated in Principle 1 of the Nuremberg Code and the informed consent section of the Federal Regulations (45 CFR 46:116) which is based, in part, upon the Nuremberg Code. Principle 1 of the Nuremberg Code states, "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

The legal documentation of informed consent is the consent form signed by both the subject and the investigator. The ethical and, indeed, legal validity of consent is, however, dependent upon the process of informed consent which requires the investigator to engage in dialogue or negotiation with the prospective subject. The consent form, therefore, should be used by the investigator as an instrument to guide the negotiations with the prospective subject. The informed consent form must embody the elements of informed consent contained in the DHHS regulations as reflected in the IRB Guidelines. The IRB will review both the consent form and the process of informed consent to ensure its acceptability.

10. Review of Investigator Qualifications

The IRB will review investigator qualifications and must be assured that (a) the investigator has the appropriate qualifications and licensure to carry out the procedures involving human subjects, and (b) that the investigator has adequate facilities and equipment to conduct the research.

11. Review of Monitoring Requirements

The IRB will determine whether or not a research project requires review more often than annually and will establish an appropriate monitoring procedure which may include observation of the consent process, observation of on-going research, and review of research records.

SECTION VI – TRAINING

A. Investigators (Principal investigator, co-investigators, and other personnel)

1. Michigan Tech IRB training requirements
   DHHS Training Requirement: The Department of Health and Human Services (DHHS) has mandated that researchers receive training in human subject protections and the ethical conduct of research. Beginning October 1, 2000, any DHHS grant application must be accompanied by a cover letter indicating that training in human subject protections has been completed.

   The training requirement set forth by DHHS can be met through participation in a computer based

training program (CBT) or tutorial.

REGARDLESS of funding source, you are required to undertake the on-line training session

Investigators including all students listed on the project, regardless of funding, are required to complete applicable on-line CITI training modules according to the type of research being conducted. You will receive a certificate of completion, and our office will be notified electronically of this completion. This education is required to be completed by all investigators for all new applications submitted for review and approval. Refresher modules must be completed to maintain an up-to-date training status. Investigators should maintain copies of all relevant training for the research team member listed in the study.

The link for more information is:
http://www.mtu.edu/research/administration/integrity-compliance/review-boards/human-subjects/human-training.html

Click on the CITI link to go to the log in and registration page. You will be able to register your affiliation with Michigan Tech and revisit the site, if needed, to complete the training.

GLOSSARY

ASSENT: A minor's (or mentally limited person's) explicit affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as assent.
CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.
DEBRIEFING: Giving subjects previously undisclosed information about the research project following completion of their participation in research.
DEAD FETUS: An *ex utero* fetus which exhibits neither heartbeat, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord if still attached.
EQUITABLE: Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.
ETHICAL CODES AND STATEMENTS OF ETHICAL PRINCIPLES: There are three major ethical codes that provide general ethical guidelines for the responsible conduct of research in the United States and which provide the basis for the federal regulations (and hence, MICHIGAN TECH'S regulations) on the protection of research involving the use of human subjects. They are the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki, all of which are available in the Compliance, Integrity and Safety Office.
FETUS: The product of conception until the pregnancy is terminated.
GUARDIAN: See Legally Authorized Representative.
HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.
INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventative procedure.
INTERACTION: Includes communication or interpersonal contact between investigator and subject.
INTERVENTION: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
IN VITRO FERTILIZATION: Any fertilization of human ova which occurs outside the body of a female.
LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body authorized under applicable state or local law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved.
MINIMAL RISK: The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
MINOR: Any person under the age of 18 years.
NONVIABLE FETUS: An *ex utero* fetus which is not viable (see Viable).
PARENT: A child's biological or adoptive parent.
PREGNANCY: The period of time from confirmation of implantation, through any of the presumptive signs of pregnancy, such as missed menses or by a medically acceptable pregnancy test, until expulsion or extraction of the fetus.
PRINCIPAL INVESTIGATOR: The scientist or scholar with primary responsibility for the design and conduct of a research project.
PRISONER: Any individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial, or sentencing.
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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record).
RESEARCH: Any systematic investigation designed to develop or contribute to generalizable knowledge. Research encompasses work which is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the subject involvement even if this work is preliminary to a more extensive study. This definition includes any systematic collection of data from human subjects which occurs in conjunction with classroom projects unless the work is done as a learning exercise for the student and will never be published or presented.
RESEARCH PROTOCOL: The procedures and rules for dealing with the subject and the records derived from the subject.
VIABLE FETUS: A fetus which is able to survive given the benefit of available medical therapy to the point of independently maintaining heart beat and respiration.
VOLUNTARY: A subject's decision to participate in research made free of coercion, duress, or undue inducement.

Addendum: This document is based upon the following federal guidelines.

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education, and Welfare.

Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks.
In addition, the following institutions shared their guidelines, procedures, and application materials for use as we developed our own. Language is taken in whole or in part from some of them to fit the situation at Michigan Technological University. We want to thank each institution listed below for their cooperation.

Human Subjects in Research: IRB Policies and Procedures, Central Michigan University, **IRB.**
Amended Policies and Procedures Pertaining to Research Involving the Use of Human Subjects, Northern Illinois University, **IRB**.
Application for Review and Approval of Activity Involving Human Subjects, Southwest Missouri State University, Human Subjects Protection Review Committee.
Ethical Principles for the Conduct of Research with Human Participants, **IRB**, St. Cloud State University.
Guidelines for Research Involving Human Subjects, Miami University Committee on the Use of Human Subjects in Research.
Guidelines for Submitting Protocols to the IRB, Ball State University **IRB**.
Human Subjects IRB, Informational Notes and Procedures Manual, Western Michigan University.
Human Subjects IRB Packet for Investigators, San Jose State University.
IRB Guidelines for the Protection of Human Subjects in Research Studies, University of Nebraska, **IRB** for the Protection of Human Research Subjects.
Protecting Human Subjects, The University of Toledo Policy for Protection of Human Subjects in Research and Investigational Activities.
Research Submissions Involving Human Subjects, Indiana University/Purdue University at Indianapolis.
Texas Woman's University Application to Human Subjects Review Committee, Human Subjects Review Committee, Texas Women's University.
UNLV Review Requirements and Procedures for Faculty and Student Research Involving Human Subjects, University of Nevada-Las Vegas.