

**Northern Michigan University
Institutional Review Board (IRB)
Human Subjects Research Policy Manual**

**College of Graduate Studies and Research
Northern Michigan University**

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Human Subjects Research Policy Manual

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(I)

Institutional Review Board Policies and Procedures
Involving the Use of Human Subjects in Research

While private and federal funding sources for research have produced an increase of beneficial knowledge through research, they have also impacted guidelines for human subjects in research. While most researchers seek to observe ethical research practices, history is replete with examples of researchers mistreating and abusing human subjects. Populations subject to misconduct have included, but are not limited to students, prisoners, disenfranchised and disadvantaged members of society, institutionalized patient populations, laboratory assistants and others. Ethical violations in research have led to national and international efforts to develop ethical principles and codes to protect the welfare and rights of human research subjects. At the forefront of such efforts are agencies and organizations such as the United States Department of Health and Human Services, the World Health Organization, the Food and Drug Administration, the National Office of Human Research Oversight, the American Psychological Association and the American Association for Counseling and Development.

Federal guidelines delineate the requirements that institutions must adhere to when using human subjects in research (Federal Policy [Common Rule] for the Protection of Human Subjects, Sections 102(f) and 103(a)), ([Code of Federal Regulations, Title 45 \[45CFR46\]](#)). Northern Michigan University (NMU) is committed to protecting the rights and welfare of all human research subjects at this institution. With this intent the university has established its Institutional Review Board (IRB).

The purpose of this manual is to disseminate and implement policies and procedures that conform to federal and when appropriate international ethical standards of research protecting human research subjects. Specifically, the procedural plan ensures that when human subjects are used in research (1) risks to subjects are minimized and are reasonable and favorable in relation to anticipated benefits; (2) legally acceptable informed consent will be obtained and documented from the subject or the subject's legally authorized representative; (3) review of the project will be undertaken to assure that the subject's rights are protected.

All research involving human subjects at Northern Michigan University, whether or not they are supported by federal, state, or private funds, will be reviewed in accordance with the guidelines outlined in this manual.

These guidelines are intended to assist the investigator in developing specific procedures for the protection of human subjects and to ensure that all applicable codes and regulations are adhered to.

A. Background and Responsibilities for Investigators

Northern Michigan University (NMU) 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 and co-investigators and all those involved in the conduct of the research, for ensuring that the rights and welfare of those subjects are adequately protected.

The following 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). The manual reflects changes included in *Revised Common Rule*, which took effect on July 1, 2018.

Current law places the burden of liability for negligence and harm directly on the *investigator* and the institution. The IRB policies and 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 also may 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 Northern Michigan University as a violation of university policies and procedures and will result in appropriate administrative action.

The Northern Michigan University Institutional Review Board (NMU-IRB) has institutional responsibility for use of human subjects in research under the auspices of, or utilizing the students, personnel, or facilities of Northern Michigan University. All projects must be accomplished in accord with this policy, and all projects covered by this policy can be undertaken only after appropriate approval and may be continued only in accordance with the terms of that approval, 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.

A pilot study is a preliminary investigation of the feasibility of a study, usually done on a small scale (approximately 10 or fewer subjects) and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. Such a pilot would not contribute to generalizable knowledge and therefore is not considered research and does not require IRB review. Data collected from a pilot study cannot be used as research data.

Medical interventions or interactions for research purposes, especially those involving invasive procedures, *do* require IRB review regardless of the size of the study.

Responsibilities of Faculty PI's of Student Research

Projects conducted by NMU undergraduate and graduate students need IRB approval if the project fits the definition of “research” and involves human participants. Such research projects require a faculty principal investigator to take responsibility for the oversight of the IRB application and all supporting materials.

When the overall objective of a class assignment is to learn about how research projects are designed and conducted and data analysis will occur for learning purposes only (e.g., to teach research methods), the research project may not constitute research as defined by federal regulations. If the project does not receive IRB approval, however, this means that at no point during or after the conclusion of the course may the results or the data be publicly disseminated (i.e., it cannot be presented in a public forum or published).

The Faculty Principal Investigator's Role

- The IRB does not have the responsibility to supervise or correct student IRB applications. This is the responsibility of the faculty principal investigator.

- A faculty principal investigator is required for all student research projects involving human participants. The faculty principal investigator will serve as the principal investigator for the student project. **The faculty principal investigator must review and approve the student application prior to IRB submission, and is responsible for the project's research integrity. The faculty principal investigator is also responsible for ensuring the application is responsive to IRB requests for revision.** The faculty principal investigator should provide detailed instructions and guidance about research designs aimed at reducing the risk to human participants, and about the IRB application process.

The data from any classroom research project that does not receive IRB approval may not be publicly disseminated.

Research as a Coursework Requirement

Research conducted within the classroom solely for pedagogical purposes does not need IRB review under the following conditions.

- the instructor's intention is to teach professional research methods, such as interviewing, surveying, or experimental design;
- the data are gathered solely for the purposes of teaching how to analyze them;
- the results will remain in the classroom.

Dissemination of the Findings:

If the results will be published or presented at a conference (whether off-campus or on-campus), or if the data is generalized in some other way, it will be necessary to obtain IRB approval with the faculty member as PI.

If a class project evolves into a research project that the student/instructor wishes to publish or generalize, then the research will need to undergo IRB review. Data collected before IRB approval **cannot** be used.

It is the responsibility of the investigator to refer his/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." The determination of the classification of the study, and the resultant appropriate review and approval, rests with the Institutional Review Board and not the researcher or Principal Investigator.

B. Definition of Human Subjects Research

A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Human subjects are defined in the [45 CFR 46.102\(f\)](#) as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with an individual or, (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

C. Ethical Principles for the Use of Human Subjects in Research

1. Subject Autonomy

- i. 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.
- ii. 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 participation in the study to make an informed decision concerning participation.

iii. *NMU Students and Employees as Subjects*

When NMU students and/or employees are being recruited as potential participants, researchers must ensure that there are additional safeguards for these participants. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to participants that neither their academic status nor grades, nor their employment, will be affected by their participation decision. If the researcher is giving students extra credit for participating, students who choose not to participate should be given alternate options for extra credit that take the same amount of time and effort that participation in the study takes. The consent form should state the alternate form of extra credit.

2. *Subject Safety*

- i. A paramount responsibility of the investigator is to protect subjects from risk. Risk can include physical or mental discomfort, harm, or danger, social embarrassment, economic burden, or legal jeopardy. 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).
- ii. 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.
- iii. 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.
- iv. 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.
- v. 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 Subject(s) and Community*

- i. Wherever possible, the research project should be designed with the intent that the knowledge gained will benefit the subjects and/or a larger community.
- ii. The benefits of the research should be made available to all subjects in the study regardless of roles in the research project. For example, positive outcomes found for any treatment group must be made available to all subjects at the completion of the study.

4. Conducting Fair and Equitable Research

- i. 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 to Participating Subjects

- ii. 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.

D. Categories of Research Involving the Use of Human Subjects

Proposed research projects involving human subjects at Northern Michigan University fall into one of four categories: (1) Non-Reviewed Research; (2) Limited Review; (3) Expedited Review; or 4) Convened IRB Review.

1. Non-Reviewed Research

- i. University classroom research conducted by faculty for learning comparisons without presentation of findings
- ii. University classroom assignments for student learning
- iii. University research for the purpose solely for in-house quality improvement

Non-Reviewed research does not relieve the investigator 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.

2. *Limited IRB Review*

Federal and University policies require that all research involving human subjects receive review and approval before the research begins; however, specific categories of research can be approved by an IRB official and do not require Full Board approval. The Limited IRB Review process is much less rigorous than an Expedited or Convened review.

The Revised Common Rule took effect in July 2018 and has increased the types of research that qualify for Limited IRB Review. If your project falls under one of the five categories listed below, denote that on the NMU IRB application and provide an explanation. These categories present benign behavioral interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on subjects, and the investigator has no reason to think subjects will find the interventions offensive or embarrassing.

- i. Research conducted in established or commonly accepted educational settings involving **normal educational practices** such as research on regular and special educational strategies, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

These classroom practices/educational methods are not likely to adversely affect classroom instruction time or student performance.

[Note: in K-12 settings an approval letter from a school administrator is required, but not informed consent from the students]

- ii. Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement) or **interviews** if the information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This educational testing can take place outside of normal classroom practices, provided that any recorded information is completely de-identified or disclosure outside of the research would not put subjects at risk of harm.

- iii. Surveys/Questionnaires, provided any disclosure of the participants' responses outside the research would not place the subjects at risk of criminal or civil liability; or would be damaging to the participants' financial standing, employability, or reputation.
- iv. Observational research (or field research) is a type of correlational (i.e., non-experimental) research in which a researcher observes ongoing behavior. Observational research is particularly prevalent in the social sciences and in marketing. It is a social research technique that involves the direct observation of phenomena in their natural setting. It is typically divided into naturalistic (or "nonparticipant") observation, and participant observation.

3. *Expedited Review*

Expedited review of certain research projects is permitted by federal policy. The expedited review procedure cannot be used in instances where identification of the participants or participants' responses would cause or place them at reasonable risk of criminal or civil liability or be damaging to the participants' psyche, employability, reputation, or financial standing, unless appropriate and reasonable protections will be executed so that risks related to the invasion of privacy and breach of confidentiality are no greater than normal. In addition, the expedited review procedure cannot be utilized with research involving vulnerable populations (Glossary of Terms) or classified research.

After reviewing an expedited proposal the subcommittee of the IRB may:

- Approve the project as submitted.
- Approve the project pending minor modification.
- Remand the project for review by the full IRB.

Research projects should not be viewed as involving minimal risks simply because they are included in the following list. Inclusion on the list simply means that the research activity is **eligible** for review through the expedited review procedure when specific circumstances of the proposed research activity involve no more than minimal risk (glossary of terms) to human subjects. Investigators

still must prepare informed consent documents which contain all relevant elements of informed consent as outlined in this manual.

Activities and Projects That May Qualify for Expedited Review:

- i. 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 decrease 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.
- ii. 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.
- iii. 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 gum base 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 subgingival 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.

- iv. 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, electromyography, 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.
- v. 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.
- vi. Collection of data through normal exertional physical tasks, such as running, jumping, lifting weights etc., under proper supervision.
- vii. Collection of data from video or image recording made for research purposes.
- viii. 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), which typically employs survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

4. *Convened IRB Review*

All research activities and projects that are not eligible for Limited or Expedited review as set forth in this manual require submission for Convened IRB review. Research proposals submitted for Convened IRB review will typically be reviewed by the Board on the second Wednesday after submission at 7:30 AM. Attendance by the Principal Investigator is required (as well as the faculty advisor for student submissions)

By majority vote of a quorum, the Institutional Review Board, may:

- Approve the project as submitted,
- Approve the project pending minor modifications as mandated by the IRB,
- Request major modifications and resubmission to the full IRB for review and approval,
- Disapprove the project.

5. *Research Conducted Cooperatively with another Institution*

The Revised Common Rule provides provisions for single-site IRB approval of multi-site cooperative research.

If a researcher at NMU plans to participate in a research study that has already been approved by the IRB of another institution, s/he still needs to submit an application for NMU's approval. Copies of the approval letter and all necessary forms (such as informed consent, interview protocol, etc.) from the other institution are required along with the application.

When soliciting participants at NMU for projects approved through a cooperating institution's IRB, the NMU co-researcher's contact information and the NMU IRB

Administrator's contact information must be provided to the participants on the informed consent form.

Section II : Instructions for Application for Approval To Use Human Subjects in Research or Classroom Situations

A. Application Instructions

Faculty who have IRB submission included as part of class coursework must meet with an IRB representative before submitting class projects to the IRB.

All investigators involved with the research project (including student researchers) must have completed, within the past four (4) years, the requisite CITI Human Subjects Research Training Modules that correspond with the type of research they are conducting. Co-investigators from other institutions may submit evidence of having taken alternate research training courses (Eg – NIH Research Ethics courses).

Link to this [site](#) and enter your NMU e-mail, and then select a password. Once you complete the modules, CITI will produce a confirmation of Completion Report. Include your CITI Completion Report as an attachment to your IRB application.

A description of how to prepare the NMU Human Subjects Research application for review by the NMU Institutional Review Board follows. Examples of completed applications are available on the NMU Human Subjects Search website.

Applications should be concise and should include required information. Copies of consent forms, questionnaires, or other instruments must be included as appendices to the electronic application document, if appropriate.

1. Description of Participants/Subjects

- i. Describe the subject population in terms of the number of subjects and age range. Include information about participants if from a vulnerable population.
- ii. Provide a rationale for the use of special classes of subjects (children, pregnant women, fetuses, mentally retarded, mentally disabled, prisoners, or other vulnerable groups).

- iii. Identify the source of the potential subject pool. If this source is a publicly available list, please indicate so. Describe the criteria and procedure used to select research participants from the pool of all possible participants.
- iv. Describe how the subjects will be selected. Will this be voluntary? Will the possibility of coercion be minimized? Are there compensations or rewards explained? (Attach advertisements or flyers, cover letters used in survey research, or scripts used in solicitation procedures, if appropriate.)
- v. Attach a letter giving approval from a representative of any agencies that will be involved with the participant recruitment and/or data collection.
- vi. Provide assurance that there will be no unauthorized access to potential subjects' private or confidential information. Document that you have the right to access the information.

2. *Instrumentation*

- i. Attach a copy of all questionnaires, interview schedules, or data collection instruments.
- ii. Describe any apparatus used for data collection.

3. *Benefits*

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

4. *Risk and Protection of Subjects*

- i. Describe the nature as well as the likelihood of potential risks or discomfort to the subjects 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).
- ii. Describe any potential reactive effects of the instrumentation as well as the treatment
- iii. Describe measures of ensuring professional intervention in the event of adverse effects to the subjects, if appropriate.

5. *Informed Consent and Child Assent*

- i. Describe the method for obtaining informed consent

- ii. Write 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 which 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 data will be held confidential, the voluntary nature of participation, and the investigators (and for student projects, the faculty advisor's) name and telephone numbers and e-mail. **(See [Section IV](#) for a detailed explanation)**

6. Confidentiality

- i. Describe 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. Explain that any information which could identify subjects will be kept for three years
 - d. The plans for disposition of information which could identify subjects, if appropriate
- ii. If you include any or all of the above information under Risks and Protection of Subjects, do not repeat that information, but state that it is included in that specific section.
- iii. 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

- iv. If the data are collected in an electronic format (audiotape, 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
- v. 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. Application for Project Renewal

IRB applications that received *Limited* or *Expedited* review are approved indefinitely as long as the project is not modified from the version that was approved. IRB applications that received *Convened* IRB approval are approved for one year. For those projects that continue beyond one year, a [Project Renewal Form](#) must be submitted.

C. Application for Project Modification

Any change in a protocol that 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 [Project Modification Form](#) for any changes in the research protocol. 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 the *Limited Review* procedure.

D. End of Project Report

For *Convened Review* projects, researchers are required to submit a [Project Completion Report](#) or request for continuation within 12 months of project approval (see B above). Failure to submit a Project Completion Form or Project Renewal Form within 12 months from the date of your approval notification will result in a suspension of Human Subjects Research privileges for **all investigators listed on the application**, until the form is submitted and approved.

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. IRB will maintain a list of approved and (i.e., the name of the principal researcher and the title of the study) for a period of ten years following the application date.

E. Submissions of a Report of Unanticipated Problem or Adverse Event

If a subject suffers an injury during research, or if there is an incident of non-compliance with IRB policies and procedures, the investigator must take immediate action to assist the subject and notify the IRB chair and NMU's IRB administrator within 48 hours. In addition, the investigator must complete an [Adverse Event Form](#).

Any incident of non-compliance with IRB policies and procedures should be reported immediately to the IRB Chair.

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 Continuing Education Office, 401 Cohodas. 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.

1. 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
2. When designing research involving prisoners, the researcher should take care to insure that:
 - i. Procedures follow DHHS guidelines listed under [46.304](#)
 - ii. Any possible advantages accruing to the prisoners are not of such magnitude that their ability to weigh the risks of the research is impaired
 - iii. 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
 - iv. 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
 - v. 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

- vi. 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 prisoner's sentences
3. Prisoners may be used in research conducted for the following purposes only: research studying the possible cause, effects, and processes of incarceration, criminal behavior, prisoners as incarcerated persons, and prisons as institutional structures provided that the study presents no more than a minimal risk and no more than inconvenience to the subjects
4. Prisoners may be used as subjects in the following types of studies: 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 of 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 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 considerations are required by the federal regulations for research involving children with exception of research conducted in educational settings.

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:

1. 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. [See Section IV.B.](#)
2. 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. (See the Models of Child Assent forms for various age groups). If the child's developmental ability precludes obtaining written assent, documented oral assent is sufficient).

C. Research Involving Participants with Impaired Decision-Making Capacity

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 a 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 [Continuing Education Office](#).

D. Research Involving Participants who are Economically or Educationally Disadvantaged

Limited comprehension of study information compromises autonomous decision making, as individuals' decisions to participate may rely on misunderstood information. This situation is ethically problematic for two reasons. First, if subjects were to fully understand study information, they might change their decisions regarding enrollment. Second, even if a given individual would not change her enrollment decision if she fully understood the nature of the research, the lack of understanding means that she does not give her informed consent, violating a basic requirement of ethical research. This well-documented phenomenon among the research subject population as a whole remains an ongoing problem for investigators aiming to secure informed consent.

Problems generally encountered with subjects' inability to understand research information are likely to be exacerbated in economically and educationally disadvantaged populations, resulting in a particular vulnerability to impaired decision making. Economically and educationally disadvantaged populations individuals are also more likely to have limited health literacy, which may significantly impair understanding of what certain medical procedures, such as a "biopsy" or "sputum test", entail. Although economic and educational disadvantages in themselves do

not necessarily imply increased difficulty understanding, educational and socioeconomic disadvantage often appear in the same populations, making it important to address this first concern.

E. Research Involving Previously Collected Health-Related Data

The new [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:

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:
 - i. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
 - ii. 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

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.

Signed informed consent is not necessary for anonymous surveys. However, informed consent is required in the form of a cover letter which accompanies the survey. The "informed consent" cover letter must contain the following elements:

1. Statement of voluntary participation.
2. Identification of the sponsoring agency.
3. Identification of the researchers, with addresses and phone numbers.

4. Brief statements of the purpose of the research.
5. Statement of how data will be used.
6. Statement that subjects may choose not to participate.

Researchers who are using anonymous surveys may submit their proposals for review as an expedited submission following the guidelines given here. A copy of the survey instruments must be submitted with the Institutional Review Board Protocol Form.

Anonymous surveys with vulnerable populations **must** be submitted for full review. Anonymous surveys with small, identifiable groups may not qualify for expedited review unless special precautions are taken. These special precautions should be addressed in the Human Subjects Protocol Form.

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 it, and how it 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.

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.

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

1. Materials are 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, etc).
2. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
3. 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 Northern Michigan University.
4. Estimate the duration of the subjects' participation
5. Describe the procedures to be followed, including how any audio or visual recording will be used. Identify any procedures which are experimental.
6. 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.
7. Discuss foreseeable risks or discomforts which may be expected from the research.
8. Discuss any foreseeable benefits to the subject or others which reasonably may be anticipated.
9. 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 the subjects along with the plans for protecting confidentiality.

10. 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.
11. Include an offer to answer any questions about the procedures. Provide the name and phone number(s) of the investigator(s) or the student investigators faculty advisor, who may be contacted for further information. Provide the contact information for the Institutional Review Board (IRB) for questions about the subjects' rights as a research participant.
12. 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 or negligence.
13. If subjects are minors (under the age of 18 years old) a parent or guardian must sign the Informed Consent Form).

Legally, children (those under the age of 18) cannot give consent on their own behalf. The consent of a child's parent(s) or a legal guardian is, therefore, required before one 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.

14. Typically, when research is to be conducted in a non-public location, the PI will be required to secure an authorization letter (email will suffice) from the site granting permission for the research to occur.

B. Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other

than the proposed research or non-research purposes) is permitted under the revised Common Rule. Future research studies may be conducted on the data. Participants do not need to be informed of the details of any specific research studies that might be conducted using their identifiable private information or identifiable biospecimens, nor the purposes of that research, given they provide broad consent.

When obtaining broad consent, the general requirements for informed consent described in Section 8.1 apply except as noted. The following elements of broad consent [§46.116(d)] shall be provided to each subject:

1. A description of any reasonably foreseeable risks or discomforts to the subject (if any future changes of procedure or uses of participant data increase the risk beyond what the participants were informed of and consented to, a new approval is required);
2. A description of any benefits to the subject or to others which may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
5. For research involving biospecimens, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will share in this commercial profit;
6. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
7. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
8. A description of the identifiable private information or identifiable bio-specimens that might be used in research, whether sharing of identifiable private information or identifiable bio-specimens might occur,

- and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
9. A description of the period of time that the identifiable private information or identifiable bio-specimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable bio-specimens may be used for research purposes (which period of time could be indefinite);
 10. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
 11. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
 12. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.
- Researchers who receive IRB approval for Broad Consent are required to submit an annual report describing the research that was done over the past year, as well as the list of co-researchers.

C. Assent Guidelines for Research Involving Minors

According to the federal regulations, children are persons who have not yet attained the legal age of consent under the applicable laws in the jurisdiction in which the research will be conducted. Generally, though not always, the age of consent is the age at which minors reach the age of majority and are considered adults. In the United States, state law dictates the age of majority. In most states, the age of majority is 18. This means that a 17 year old may be considered a child when applying the federal regulations for protecting research subjects.

Investigators should be aware that the age of majority might be quite different in other countries. It is also possible that a nation may have no legal definition of majority. In such cases investigators will have to rely on community standards. For example, a researcher in Sierra Leone found that adulthood for the male population he wished to study was conferred through a Shamanic initiation process.

When working with children, parents (or legal guardians) must provide permission for their children (or wards) to participate in research and for the researcher to contact the children. Children then provide their assent to become subjects. Assent is a child's affirmative agreement to participate. The absence of dissent should not be construed as assent when the child is old enough that this is meaningful. Generally, parental permission can only override a child's dissent when the health of the child is at stake (adapted from [Hicks, 2009](#)).

Assent forms for children must contain simple language written at the appropriate educational level of the youngest prospective subject. To check the reading (grade) level of a document using Microsoft Word, use the following steps:

- Click the **Microsoft Office Button**, and then click **Word Options**.
- Click **Proofing**.
- Make sure **Check grammar with spelling** is selected.
- Under **When correcting grammar in Word**, select the **Show readability statistics** check box.
- After you enable this feature, open a document that you want to check, and **check the spelling**. When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

Section V: Data Storage Guidelines

Data storage and security is critical. You should ensure that all hard copy and electronic data are securely stored to prevent unauthorized access, disclosure, or loss. Hard copy records should be stored in a manner that limits access to only authorized individuals. For example, filing cabinets/areas should be locked. Electronic data should be saved on a device that has the appropriate security safeguards such as unique identification of authorized users, password protection, automated operating system patch (bug fix) management, anti-virus controls,

firewall configuration, and scheduled and automatic backups to protect against data loss or theft.

Researchers possess a strong sense of ownership for their data and consequently often store data on their personal computers; however, data collected as part of research is property of NMU. NMU pays (or permits) researchers to produce the work, and as a result the work/data are the institution's property. Though researchers may store data, NMU holds the rights to the data. The NMU IRB may request researchers to turn over data at any point throughout the data retention window, until the data are destroyed (see the information below on Investigator Requirements for Retaining Research Data).

If a researcher leaves NMU, s/he must either turn over the data to the corresponding NMU Department Head or leave contact information in the event the NMU IRB needs access to the data during the data retention window. If there are questions or allegations about the validity of the data or appropriate conduct of the research, researchers must retain all of the original research data until such questions or allegations have been completely resolved.

Investigator Requirements for Retaining Research Data

Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed. The question then becomes: How long do you have to keep the records after the completion of the research? Unfortunately there are several different regulations each of which has different requirements. As a result, researchers must retain their records for as long as the applicable regulations require.

- **NMU Requirements:** All research at NMU is bound by 45 CFR 46 which requires research records to be retained for at least three (3) years after the completion of the research.
- **HIPAA Requirements:** Any research that involves collecting identifiable health information is subject to HIPAA requirements. As a result records must be retained for a minimum of 6 years after each subject signed an authorization.
- **FDA Requirements:** Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. *Please note - this length of time can be much greater than 2 years. You should receive written confirmation from the sponsor and/or FDA granting permission to destroy the records.* (21CFR312.62.c)

- **VA Requirements:** Any research conducted at the VA must be retained for a minimum of 5 years after the completion of the study and in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors, as described in 1200.5, section 7.j

http://www1.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=418

IN SUMMARY:

1. Research records must be maintained a minimum of three years after the research is completed and the study closed with the IRB.
2. Records may need to be kept longer if other requirements apply.

Section VI: Guidelines for Review by Institutional Review Board

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.

A. Review of 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.

B. 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.

C. 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. Poorly designed research proposals that may

result in the lack of generalizable data or activities that unnecessarily duplicate previous experiments can be rejected by the IRB.

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 the experimental design must include a post-study debriefing unless a waiver is granted by the IRB.

D. Review of 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, skinfold 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.

E. 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.

F. 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.

1. 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.
2. 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.

G. Review of Subject Remuneration

1. *Principal of Incentive and Reimbursement:* The researcher may pay research participants, but the payment for participation is not considered a benefit but rather a recruitment incentive or reimbursement for time and effort. All payments to participants in research must be fair and equitable.
2. *Principle of Reasonable Remuneration:* The IRB will review and determine that the amount is reasonable and not so large as to interfere with the ability of the participant to give informed consent without the possibility of coercion or undue influence. While the Federal Regulations do not specifically state how much researchers should pay participants or what that payment should look like, the IRB will apply a principle of reasonable compensation as it reviews participant payment for their time, effort and inconvenience. The IRB will also take into account information from the make-up of the sampling population, and the community environment and culture as it evaluates the appropriateness of participant payment.
3. *Method of Disbursement:* Northern Michigan University must satisfy certain IRS reporting obligations when making payments to human subjects. These

payments to any one (1) individual that exceed the \$600 threshold during a calendar year are subject to certain IRS reporting regulations. The individual may be contacted if a W9 form is needed to obtain a tax identification number.

Reasonable remuneration (includes cash, gift cards, or gifts) may be made to subjects participating in the project. The PI must maintain a log of the human subjects participating. The remuneration log (add link to remuneration log) must include a statement signed and dated by the research participant stating the amount they received. This log must be submitted to the Controller Office each semester. For studies in which participants are Anonymous the remuneration log must be maintained by the PI. Per IRS requirements, the remuneration log will be reviewed by the Grants Accountant or Controller.

4. *Payments to Nonresident Foreign Nationals:* Researchers anticipating payments to nonresident nationals should contact Accounts Payable PRIOR to making such payments. Payments made to research participants who are nonresident nationals must be paid by Accounts Payable and will be reported on IRS Form 1042-S, Foreign Person's U.S. Source Income Subject to Withholding, regardless of the dollar amount. Due to special IRS withholding requirements, University policy does not allow cash or cash equivalent (such as gift cards/certificates) payments to be paid to nonresident nationals. All payments to nonresident nationals are subject to 30% federal withholding for income tax.
5. *Research Participant Payments:* Employees - All payments made to an employee of the university are taxable regardless of the amount. This includes cash payments and gift cards, as well as direct deposit or ACH. Employee research participant payments must be reported to Payroll and are included on the employees W2. The Controller Office will forward the employee information to Payroll.
6. *Advertising Remuneration:* Your advertisement may state that participants will be paid, but should not emphasize the payment or the amount to be paid, by such means as large or bold type. Examples of remuneration include: small gifts, payments, compensation, reimbursement, services without charge or extra credit points. Researchers cannot pay subjects to take risk.

H. 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 NMU Human Subjects Research Policy Manual investigators, the IRB will review the justification for sharing these data and determine acceptability.

I. 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.

J. 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.

K. 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 VII: Institutional Review Board Procedures

Federal standards and policies require that full authority and responsibility for safeguarding the rights and welfare of human subjects in research are placed with a committee referred to as the Institutional Review Board, the local administrative unit established to ensure protection of the rights and welfare of human subjects used in research conducted under the auspices of NMU. The IRB reports directly to the IRB Administrator, who is appointed by the University to oversee research activities. Under University policy, the IRB has the authority to approve, require modification of, or disapprove any and all research activities that fall within its jurisdiction as specified by federal or local institutional policy.

Research approved by the IRB may be subject to review and disapproval by institutional officials; however, institutional officials may not approve research disapproved by the IRB. The NMU Institutional Review Board provides assurances to research subjects that every reasonable attempt has been made to protect their rights and safety as research subjects.

A. IRB Administrator

The ultimate responsibility of the IRB resides with the NMU Administrator (typically Dean of Graduate Studies) who serves as the IRB Administrator. The IRB Administrator is responsible for ensuring the NMU IRB has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects research. The IRB Administrator is legally authorized to represent NMU. He/she is the signatory of the FWA and assumes the obligations of the FWA.

The IRB Administrator holds ultimate responsibility for

1. oversight of the Institutional Review Board (IRB);
2. oversight over the conduct of research conducted by all NMU investigators;
3. assuring that IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
4. assuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
5. submitting, implementing, and maintaining an approved FWA through the VPR/DGS and the Department of Health and Human Services Office of Human Research Protection (OHRP).
6. managing the budget of the NMU IRB;
7. working closely with the Chair of the IRB and on the development of policy and procedures as well as organizing and documenting the review process;
8. working closely with the Chair of the IRB and on developing, managing and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the IRB program.

B. IRB Chair

The NMU IRB Administrator, in consultation with the University, will appoint a Chair of the IRB to serve in a year-round capacity. The IRB Chair must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators and other professional and nonprofessional sources.

The IRB Chair is responsible for:

1. assisting researchers with questions about the IRB process;
2. in consultation with IRB staff, reviewing all applications and determining the level of review required.
3. conducting meetings of the Convened IRB
4. in consultation with IRB staff, designating other IRB members to perform duties, such as serving on Expedited Review Committees

C. IRB Membership Criteria

NMU's IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

- The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. [§46.107]

D. Appointment Procedures

In consultation with the IRB Chair, the IRB Administrator shall appoint members to the IRB.

E. Removal Procedures

In consultation with the IRB Chair, the IRB Administrator shall remove members from the IRB for such reasons as excessive absences or failure to meet deadlines.

F. IRB Functions and Operations

The IRB or its members shall review **all** research involving human subjects, including research funded by federal, state, private, or corporate funds for which a representative of Northern Michigan University must sign; unfunded research involving NMU facilities or staff; graduate and undergraduate student research projects reaching beyond the immediate classroom. The IRB will follow the procedures outlined in this manual for carrying out its initial and ongoing review of research as well as for reporting its conclusions and actions to the researcher and the institution.

The review of proposed research and the ongoing periodic review of approved research by the committee will include a critical review of the procedures used to protect the rights and welfare of human subjects to ensure adequate protection; ensuring that the risks to an individual (including physical, psychological, and social) are outweighed by potential benefits to society; and ensuring that a legally acceptable informed consent will be obtained from the subject or the subject's legally authorized representative and documented. The critical review will include a review of the research design to ensure that the design is consistent with the protection of human subjects.

Any serious or ongoing noncompliance on the part of the researcher will result in a report in writing to the IRB Administrator of any with the requirements and determinations of the IRB. The IRB Administrator, following confirmation that noncompliance has taken place, will contact the researcher's immediate supervisor and, where required by codes or regulations, notify any appropriate federal agency in writing.

G. Committee Procedures

1. Meetings

- i. The IRB shall meet periodically throughout the year, as needed to conduct Convened Reviews. The applicant must be present at the Full Review meeting. For student researchers, their faculty advisor is strongly encouraged to attend as well. All items relevant to the review of

submitted proposals will be sent to committee members at least 8 days before the scheduled meeting date to provide sufficient time for review.

- ii. A majority of the members must be present at an IRB meeting to approve human subjects applications under Convened Review. Approval requires a majority vote of those present. The NMU IRB may conduct business electronically, for example via email. In such cases, a majority of the IRB who respond within 10 days of the motion must vote in the affirmative to approve motions.
- iii. Expedited Review meetings may be conducted electronically by three-member subcommittees of the IRB. The chair of the subcommittee reports to the IRB chair and the IRB administrator the actions of the subcommittee. Expedited reviews are eligible for the decisions of approval similar to Convened Review applications, as listed below.
- iv. Minutes shall be taken of every meeting. An opportunity to review, revise, and amend the minutes will be given at the next meeting.
- v. Complete copies of all research proposals requiring review by the IRB shall be kept in an institutional file in the Office of the IRB Administrator. If renewal or modifications are made by the investigator and are approved by the committee, they shall be kept in the same file.

2. *IRB decisions*

Decisions may be made by the Convened IRB, a subcommittee appointed for expedited approval, the IRB Chair, or the IRB administrator, depending upon the qualification of the application. Following review, the IRB or subcommittee chair will send a notification of committee action to the principal investigator.

The notification of committee action includes the following decisions:

- i. **Approve as Submitted**

The project may be approved as submitted if the principal investigator has met all requirements and has taken practical steps to minimize the risk to subjects and maximize potential benefits.

If the decision of the committee is to approve the project, the researcher will receive a project number to be included on all materials given to participants.

ii. **Approve with Minor Modification**

If the IRB committee determines that minor changes are needed to the application and/or associated documents, the committee chair will provide the principal investigator with a complete list of required changes. In addition, the committee may include recommended changes.

The principal investigator is responsible for modifying the research proposal approved with minor modifications. The researcher shall forward to the chair a revised version of the research proposal which includes the items mandated by the IRB. All revisions should be completed in **red boldface** type so they can be easily identified by the reviewer.

Once the chair accepts the minor revisions, the principal investigator will be issued a project number to be included on all materials given to participants. The investigator shall not undertake the proposed project until notification by IRB that the modifications have been accepted.

iii. **Major Modifications Needed for Approval**

If an Expedited or Full Review application requires major modifications, the researcher is required to resubmit the proposed project to the Convened IRB for review. The revised proposal must address the concerns of the IRB and present compelling evidence that the risks have been minimized.

iv. **Disapproval**

Projects that are disapproved by the IRB are returned to the principal investigator with a complete explanation for the disapproval.

3. *Committee Actions in Response to Non-Compliance*

- i. The principal investigator is responsible for ensuring that all co-investigators adhere to the principles and practices set forth in this manual. Failure to do so will result in a notification of non-compliance to the IRB Administrator who is responsible for following the procedures for responding to allegations of non-compliance.
- ii. These procedures allow the investigator to respond to allegations of non-compliance.
- iii. Where non-compliance is verified, the investigator's supervisor and dean will be notified. In addition, notification will be sent to any federal agencies as regulations require.

Section VIII: Glossary Of Terms

Institutional Review Board (IRB)

Northern Michigan University

ADVERSE EFFECT An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

ANONYMIZED means that data or bio-specimens do not contain any identifying information and they cannot be linked to any identifiable person.

ASSENT Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

ASSURANCE A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy §____. 103].

AUTHORIZED INSTITUTIONAL OFFICIAL An officer of an institution who has the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. At Northern Michigan University, this individual is identified as the IRB Administrator.

AUTONOMY Personal capacity to consider alternatives makes choices, and act without undue influence or interference of others.

BELMONT REPORT A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

BENEFICENCE An ethical principle discussed in the *Belmont Report* that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFIT A valued or desired outcome; an advantage.

CHILDREN Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [[45 CFR 46.401\(a\)](#)].

CDC Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.

CLINICAL TRIAL: A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

COGNITIVELY IMPAIRED Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

COHORT A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

COMPENSATION Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (*compare to remuneration.*)

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 without permission in ways that are inconsistent with the understanding of the original disclosure.

CONTROL (SUBJECTS) or CONTROLS Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

CONTRAINDICATED Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).

DEBRIEFING Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from Standard English, in which debriefing is obtained rather than imparting information.)

DE-IDENTIFIED means that identifiers have been removed from data biospecimens; a code may link individual records or specimens to identifiable persons. The requirement for IRB review depends on who deidentified the data/biospecimens and who has access to the linking code.

DECLARATION OF HELSINKI A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

DEPENDENT VARIABLES The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

DESCRIPTIVE STUDY Any study that is not truly experimental (e.g., quasi-experimental studies, correlation studies, record reviews, case histories, and observational studies).

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

DIAGNOSTIC (PROCEDURE) Tests used to identify a disorder or disease in a living person.

DRUG Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

EMANCIPATED MINOR A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation (*See mature minor*).

EQUITABLE Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed [Federal Policy ____ .111(a)(3)].

ETHNOGRAPHIC RESEARCH Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (*See fieldwork*).

EXPEDITED REVIEW Review of proposed research by the IRB chair or a group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy ____.110].

EXPERIMENTAL STUDY A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (*See also quasi-experimental study*.)

FDA Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

FEDERAL POLICY The federal policy that provides regulations for the involvement of human subjects in research. The policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy (also known as the "Common Rule")

FETUS The product of conception until the pregnancy is terminated.

FIELDWORK Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (*See also: ethnographic research*.)

GRANT Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare contract*.)

GUARDIAN An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [[45 CFR 46.402\(3\)](#)].

HUMAN SUBJECTS Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as living individual(s) about whom an investigator conducting research obtains: (1) data

through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy ____.102(f)]

INDEPENDENT VARIABLES The conditions of an experiment that are systematically manipulated by the investigator.

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 preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy 116; 21 CFR 50.20 and 50.25].

INSTITUTION (1) Any public or private entity or agency (including federal, state, and local agencies) [Federal Policy ____.102(b)].

INSTITUTION (2) A residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease hospital; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential schools for the mentally or physically handicapped; and homes for dependent and neglected children.

INSTITUTIONAL OFFICER The individual responsible for oversight of research within the organization. At Northern Michigan University, the Institutional Officer is designated as the Dean of Graduate Studies and Research.

INSTITUTIONAL REVIEW BOARD A specially constituted review body established or designed by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy ____.102(g), ____.108, ____.109]. At NMU, the IRB is named the Institutional Review Board (IRB).

INSTITUTIONALIZED Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

INSTITUTIONALIZED COGNITIVELY IMPAIRED Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the retarded).

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.

INVESTIGATOR In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (*See also principal investigator.*)

IN VITRO Literally, “in glass” or “test tube”; used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from *in vivo*.

IN VIVO Literally, “in the living body”; processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (*in vitro*).

IRB The Institutional Review Board at NMU, known as the IRB.

JUSTICE An ethical principle discussed in the *Belmont Report* requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

LEGALLY AUTHORIZED REPRESENTATIVE A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research [Federal Policy ____.102(c)].

MEDICAL DEVICE A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

METABOLISM (OF A DRUG) The manner in which a drug is acted upon (taken up, converted to other substances, and excreted) by various organs of the body.

MINIMAL RISK A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [4646.102(i)]. For example, the risk of drawing a small amount of blood

from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults. (See [45 CFR 46.303\(d\)](#))

MINOR Any person under the age of 18 years.

MONITORING The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.

NIH National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

NONAFFILIATED MEMBER Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, or homemaker).

NONSIGNIFICANT RISK DEVICE An investigational medical device that does not present significant risk to the patient. (See also *significant risk device*.)

NON-THERAPEUTIC RESEARCH Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.

NUREMBERG CODE A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during 1950s and 1960s for protecting human subjects.

PARENT A child's biological or adoptive parent .

PERMISSION The agreement of parents(s) or guardian to the participation of their child or ward in research [[45 CFR 46.402\(c\)](#)].

PLACEBO A chemically inert substance given in the guise of medicine for the psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.

PREGNANCY The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [[45 CFR 46.203\(b\)](#)]. This “confirmation” may be in error, but, for research

purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

PRINCIPAL INVESTIGATOR A scientist or scholar with primary responsibility for the design and conduct of a research project. Student research requires oversight by a faculty advisor. (*See also investigator.*)

PRISONER An individual involuntarily confined in a penal institution, including persons (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [[45 CFR 46.303 \(c\)](#)].

PRIVACY Control over extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

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).

PROPHYLACTIC Preventive or protective; a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.

PROSPECTIVE STUDIES Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

QUASI-EXPERIMENTAL STUDY A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups (*See also experimental study.*)

RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

REMUNERATION Payment for participation in research. (NOTE: It is wise to confine use of the term “compensation” to payment or provision of care for research-related injuries.) (*Compare compensation.*)

RESEARCH A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. [46.102(d)]

RESEARCH PROTOCOL The procedures and rules for dealing with the subject and the records derived from the subject.

RESPECT FOR PERSONS An ethical principle discussed in the *Belmont Report* requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

REVIEW (OF RESEARCH) The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy __.108(e)].

RISK The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.” (*See also minimal risk*).

SECONDARY RESEARCH means conducting research using data or bio-specimens originally

collected for another purpose, which may or may not have been research. The requirements for IRB review and informed consent depend on the circumstances under which the data were collected and whether the data can be linked to individuals.

SOCIAL EXPERIMENTATION Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

SPONSOR (OF A DRUG TRIAL) A person or entity that initiates a clinical investigation of a drug – usually the drug manufacturer or research institution that developed the drug. The sponsor does not actually conduct the investigation, but rather distributes the new drug to investigators and physicians for clinical trials. The drug is administered to subjects under the immediate direction of an investigator who is also not a sponsor. A clinical investigator may, however, serve as a sponsor-investigator. The sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable law and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

SPONSOR-INVESTIGATOR An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

STERILITY (1) The absence of viable contaminating microorganisms; aseptic state.

STERILITY (2) The inability to procreate; the inability to conceive or induce conception.

SUBJECTS (HUMAN) *See human subjects.*

SURVEYS Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

THERAPY Treatment intended and expected to alleviate a disease or disorder.

VACCINE A biologic product generally made from an infectious agent or its components – a virus, bacterium, or other microorganism – that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be bio-chemically synthesized or made through recombinant DNA techniques.

VARIABLE (NOUN) An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor *affecting* the outcome) of that intervention.

VOLUNTARY Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATIONS Human subjects who are physically or mentally disabled, children, addicts, prisoners, parolees, pregnant women and fetuses, and others who are in conditions of dependency [[Title 45 CFR part 46, parts A-D and CFR 46.103](#)].