

University Policies

Policy Name: Protection of Human Subjects in Research	Effective Date: July 15, 2009
Custodian of Policy: Vice President for Academic Affairs	Last Review: Unknown
	Next Review: September, 2014

Policy:

All research activity involving human subjects conducted at or under the auspices of Minnesota State University, Mankato must have Institutional Review Board (IRB) approval. In deciding if a proposed activity requires IRB approval, it must be determined if the activity involves human subjects and if it is research. For IRB purposes these decisions are based on the criteria set forth in the federal regulations.

Human subjects are involved if: a) there is an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion, in the absence of this research, or b) identifiable private data/information will be obtained for this research in a form associable with the individual. For example, secondary analysis of aggregate data does not require IRB approval.

The purpose of the IRB is to protect the welfare and rights of human research subjects. It primarily accomplishes this by reviewing proposals for research and determining if the subjects will be adequately protected and ethically treated. The board is also responsible for investigating concerns raised by research subjects, for ensuring compliance with the board's decisions, and for informing the University community about the ethical treatment of research subjects.

For IRB purposes, research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This generally excludes purely pedagogical classroom exercises especially if they are conducted solely in the classroom (not generalizable), internal program assessment such as teacher evaluations (not generalizable), and the treatment of patients or clients (not a systematic investigation). For example, an investigation undertaken solely for a class in which there are no plans for publication or presentation outside the class would not be within the purview of the IRB. Researchers are strongly urged to consult with the IRB Administrator, the IRB Coordinator, the IRB Chair, or Co-Chair if they think their activities may not require IRB approval.

Procedures:

IRB Review Criteria

In reviewing proposals the IRB considers the following general criteria:

- a. Are risks and discomforts to subjects minimized?
- b. Are risks and discomforts to subjects reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result? Although the IRB does not specifically evaluate the quality of the proposed research, it may become relevant in determining if potential benefits outweigh risks.
- c. Will voluntary and informed consent to participate in research be obtained from each subject or the subject's legally authorized representative and will it be appropriately documented? The consent process must permit the participant or legally authorized representative to exercise free power of choice without undue inducement or any element of deceit, fraud, force, duress, or other form of coercion or constraint. Please see the section on Informed Consent for additional information.
- d. Will the privacy of subjects and confidentiality or anonymity of data be protected?

IRB Review Levels and Time Required for Approval

The IRB Administrator determines what level of review is required for the proposal. There are three levels of review depending on the nature of the involvement of human subjects, the level of risk to the participants, and whether the project involves vulnerable subjects.

Proposals eligible for **Level I** review should fall under certain categories of activities involving less than a minimal risk, and not involving special or vulnerable populations (see description of vulnerable populations elsewhere in this policy). Level I reviews are conducted by the IRB Coordinator and the turnaround time is minimally two days. For paper versions of IRB proposals, researchers who believe that their project is a Level I review must attach the Level I Review Checklist.

Level II proposals involve minimal or less risk. Proposals that are not clearly Level I or are determined to be at Level II are forwarded to the IRB Chair or Co-Chair. If the Chair or Co-Chair determines a proposal is Level I or II, the proposal can be approved. However, many proposals require modifications prior to approval. If modifications are required, the proposal contact person will be sent a notice describing the required modifications or asking for clarification. If the Chair or Co-Chair decides the proposal requires a more extensive review (Level III), it is scheduled for review by the full IRB. For Level II review, the minimum time for the initial review is at least two weeks. Required modifications will lengthen the time for approval.

Level III proposals involve greater than minimal risk and require approval by the full IRB. At the meeting the board discusses the proposal, votes to approve, disapprove or to require modifications. Modifications are often required, and a liaison is assigned from the board to help the researchers comply with the Board's requirements. When the required modifications are made to the liaison's satisfaction, the revised proposal is forwarded to the Chair or Co-Chair. If the Chair or Co-Chair concurs, the project is approved. For Level III review, proposals are reviewed at the next available board meeting. The minimum time for a full board review is approximately 3 weeks and may be as long as 6 weeks. Again, modifications will extend the time required for approval.

Researchers are encouraged to submit the IRB proposal at least two months before the research is to begin. Upon IRB approval, researchers will be notified of approval. All approvals are valid for one year. Research projects extending beyond a year must submit a request for continuing review (<http://grad.mnsu.edu/irb/continuingreview.pdf>). If changes are made to a project after it has been approved, these changes must be approved by the IRB before they are implemented.

The IRB Proposal

- a. In order to protect subjects and student investigators, the IRB requires that the principal investigator (PI) must be an MSU faculty member or continuing professional MSU employee. Students are not

permitted to act as the sole or principal investigator on an IRB proposal.

b. A research proposal is written following the guidelines and outline available at <http://grad.mnsu.edu/irb>. The IRB proposal has a very different purpose than the thesis proposal and should be specifically written to address IRB concerns.

Informed Consent

A major component of any proposal is the method by which the researchers will obtain voluntary and informed consent from subjects. Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether to participate as a research subject. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. In seeking informed consent the following information should be provided to the subject:

a. A statement that the study involves research, an explanation of the purposes of the research and who will be conducting the research, expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. A description of any reasonably foreseeable risks or discomforts to the subject (again, these may be emotional, social, financial, or physical risks);

c. A description of any benefits to the subject or to others which may reasonably be expected from the research;

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. A description of how the confidentiality of records identifying the subject will be maintained;

f. For research involving more than minimal risk, an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. An explanation of whom to contact for answers to pertinent questions about the research (usually the investigators), research subjects' rights (usually the IRB Administrator), and whom to contact in the event of a research-related injury to the subject (usually the IRB Administrator);

h. 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.

When appropriate, one or more of the following elements should also be provided to each subject:

a. A statement that a particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. Any additional costs to the subject that may result from participation in the research;

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

f. The approximate number of subjects involved in the study.

Generally written consent will be obtained. In cases of greater than minimal risk, consent must be written. Under some circumstances involving less than minimal risk, documented oral consent may be adequate.

Copies of signed consent documents must be retained by the PI or secondary investigator for three years after completion of the research and must be available for IRB review if necessary.

Special Circumstances

Children or minors as research subjects

Permission is required from a parent or guardian when research subjects are minors (under the age of 18). In addition, assent should also be obtained from the subjects. This will require explaining what their participation means and their rights in age appropriate language.

Other vulnerable populations as research subjects

Vulnerable/special populations include those subjects who, as outlined in state and federal regulations, must be provided extra protection. This includes but is not limited to minors, prisoners, fetuses/pregnant women, elderly, and cognitively impaired individuals.

FDA guidelines (Federal Register: May 9, 1997, Volume 62, Number 90, page 25695) broaden the scope of different types of "vulnerable subjects" to include

"individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, of a retaliatory response from senior members of the hierarchy or institution in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects may include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency rooms, ethnic minority groups, homeless persons, refugees, children, and those incapable of giving consent."

Other groups, such as ethnic minorities, the economically disadvantaged, the very sick and the institutionalized are described as vulnerable populations by the Belmont Report and are therefore provided similar protection when used as research subjects. Some groups are not considered vulnerable populations if included in a general population.

Whenever potential subjects are persons of diminished capacity and capable of giving assent, the researcher must obtain their assent in addition to obtaining permission to participate in research from their guardian before involving the individual in a study.

Surveys and questionnaires

For surveys and questionnaires that do not involve sensitive topics or minors, return of the questionnaire can be taken as implying consent. However, a cover letter must be included which contains the elements

of consent and gives enough information about the survey that the subjects can choose to participate or not.

With surveys, volunteer subjects deserve to know the purpose of the survey. The argument that the results would be seriously biased if subjects are informed is not an adequate justification for failing to inform.

Sensitive questions

Questions or items on the following topics will require additional protection of subjects' privacy. Parents or guardians and subjects must be informed of the sensitive questions before they give permission or consent to participate. Generally, information on these topics will be gathered anonymously.

- a. Information pertaining to illegal, anti-social, self-incriminating, and demeaning behavior;
- b. Information relating to the use of alcohol, drugs, or other addictive products;
- c. Information relating to sexual attitudes, preferences, or practices;
- d. Information that if released could reasonably be expected to damage an individual's financial standing, employability, or reputation within the community;
- e. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- f. Information pertaining to an individual's psychological well-being or mental health;
- g. Information relating to a subject's political affiliations;
- h. Critical appraisals of other individuals with whom the subject has close family relationships;
- i. Income, other than that required by law to determine eligibility for participation in a program or for receiving assistance under a program.

Audiotaping, videotaping, and photographing

- a. Subjects must be advised that their participation includes the use of taping or photographing;
- b. Before consenting to being taped (audio or video) or photographed, subjects should be informed of the current and planned use of the materials including storage and access by persons other than the researcher. Subjects must be advised when tapes or photographs will be erased or destroyed;
- c. This permission will normally be included in the consent form. If consent forms are not used, the elements of informed consent must be explained to the subjects and a release must be obtained. This release statement may be included as a preamble to the taped procedure;
- d. The researcher must make proper arrangements for secure storage of all audio and video tapes and assure that their use complies with the guidelines outlined in the informed consent/release form. Plans may include storage, erasing, or destroying after a given time period.

Other participating institutions or sites

In cases where subjects are recruited from other institutions (hospitals, community agencies, schools,

etc.), the first contact with potential subjects should be made by institutional staff who, after outlining the researcher's interest and obtaining the potential subject's permission, will refer the person to the researcher or vice versa. This may also be done by a letter from the researcher which is distributed by the institution. If other institutions are cooperating with the researcher, a letter from the institution indicating the nature of that cooperation should be included with the IRB proposal.

Access to medical and educational records

A researcher may have access to institutional records, if the institution agrees in writing to the accessing and conforms to state guidelines for such access. A copy of the permission letter to access records must be provided to the IRB. The researcher may not obtain names or other identifiers from the records. Access to medical or educational records may require additional permission from the subjects.

IRB Meeting Schedule

The full board meets monthly during the academic year. The schedule for these meetings is available on the College of Graduate Studies and Research website (<http://grad.mnsu.edu/irb/dates.html>). The IRB does not typically meet during the summer, although proposals are accepted for the next academic year, and Level I proposals continue to be reviewed and approved.

For More Information, Forms, and IRB Guidelines

College of Graduate Studies and Research
Minnesota State University, Mankato
115 Alumni Foundation Building
Mankato, MN 56001
Phone: 507-389-2321; Fax: 507-389-5974
E-mail: grad@mnsu.edu
grad.mnsu.edu

Policy Rationale:

Description of the IRB

The Minnesota State University, Mankato Institutional Review Board for the Protection of Human Subjects in Research (IRB) is a standing committee of the University composed of faculty, administrators, and community members. The IRB is responsible for protecting the rights and welfare of human research subjects or participants. The IRB is governed by University policy as described in The Policies and Procedures Governing the Participation of Human Subjects in Research at Minnesota State University, Mankato (<http://grad.mnsu.edu/irb/manual.html>). This policy is based on Title 45 Part 46 of the Code of Federal Regulations (45CFR46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). Some aspects of University policy are more stringent than the federal regulations. Additionally, the IRB is informed by a number of other documents addressing the ethical treatment of research subjects including Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report) (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>) by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. While this information packet is intended to provide a summary of relevant parts of the policy, it is not intended to replace the policy.