Minnesota State University, Mankato University Policy	
Policy Name: Protection of Human Subjects in Research	**Effective Date of Last Revision** August 1, 2015
Custodian of Policy: Provost and Senior Vice President for Academic Affairs	**Date of Last Review** September 2014
Date of Adoption July 15, 2009	**Date of Next Review** September 2022

Policy

The purpose of the Institutional Review Board (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.

All research activity involving human subjects conducted at or under the auspices of Minnesota State University, Mankato must have 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 federal regulations. (http://www.hhs.gov/ohrp/-human subjects/guidance/45cfr46.htm).

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. ~~. Secondary analysis of aggregate data does not require IRB approval.~~

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~~Director of the IRB if they think their activities may not requireIRB approval.

Procedures

All IRB procedures are found in the IRB manual that can be found at http://grad.mnsu.edu/irb/manual.html.

For more information about the rights of research subjects, contact:
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Institutional Review Board
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http://grad.mnsu.edu/irb/

Rationale

The Minnesota State University, Mankato Institutional Review Board for the Protection of Human Subjects in Research is a standing committee of the University composed of faculty, graduate students, 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 Title 45 Part 46 of the Code of Federal Regulations (45CFR46) (http://www.hhs.gov/ohrp/ human subjects/guidance/45cfr46.htm) The Policies and Procedures Governing the Participation of Human Subjects in Research at Minnesota State University, Mankato (http://grad.mnsu.edu/irb/manual.html) are based on Title 45 Part 46 of the Code of Federal Regulations (45CFR46). 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.

History of Revisions
8/1/2015 – Standard Policy Review
7/15/2009 – Policy Adopted