

METROPOLITAN STATE UNIVERSITY REGULATIONS



Human Subjects Research Review Policy

University Policy # 2060

Section 1. Policy

It is the responsibility of Metropolitan State University to ensure that the rights and welfare of human subjects participating in any research affiliated with the university be adequately protected. It is also the university's responsibility to ensure that all research participants are fully informed regarding the research and that they participate willingly and are free to withdraw from the study at any time without penalty. Participants must also be guaranteed freedom from coercion and undesirable consequences, and that any identifying information relating to the conduct or the outcomes of the research will be kept confidential. The university has the dual obligation of supporting both the academic freedom of the researcher and protecting the rights of human subjects participants. These policies and procedures are intended to protect research subjects from harm by meeting professional, university, ethical and federal standards without limiting the pursuit of any systematic course of study. The Code of Federal Regulations that sets policy for institutional review boards (Title 45 Part 46) can be found on the web at: <http://ohsr.od.nih.gov/guidelines/45cfr46.html>. In future reference to this policy the symbol § indicates the paragraph of the CFR.

Section 2. Authority

This policy is issued pursuant to the authority granted under the Rules and Regulations of the Minnesota State Colleges and Universities System.

Section 3. Effective Date

This policy shall become effective upon signature by the president, and remain in effect until modified or expressly revoked.

Section 4. Responsibility

The responsibility for implementation of this regulation is assigned to the Office of the Provost and Vice President for Academic Affairs. In addition, the Provost and Vice President for Academic Affairs is responsible for assuring compliance with federal policy as provided in §46.103.

Section 5. Definitions

Research is any systematic investigation designed to develop or contribute generalizable knowledge. This includes both original studies and replications of existing studies performed by faculty, students or others (§46.102(d)).

Human subject means an individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the 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 (§46.102(f)).

HSRB means a human subjects review board established in accord with and for the purposes expressed in this policy (§46.102(g)).

HSRB approval means the determination of the HSRB that the research has been reviewed and may be conducted within the constraints set forth by the HSRB and by other institutional and federal requirements (§46.102(h)).

Section 6. Requirements

All research involving human subjects, as defined above, must be submitted to the HSRB for review and approval. No research activities, including recruitment of participants, can occur until the research has been approved.

It is expected that human subjects research proposals will satisfy the following conditions:

- A. **Minimal Risk:** Research procedures should be designed so that the probability and magnitude of physical, psychological or social 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. Any possible risks imposed must be weighed against the scientific importance and the potential benefits of the research (§46.102(i)).
- B. **Confidentiality:** Research procedures shall not disclose confidential information, including names and/or salient individual identifying characteristics, to other than the investigator(s) and their research staff. Further, adequate provision must be made to protect the confidentiality of information that is to be retained over an extended period of time.
- C. **Informed Consent:** Participants will be clearly informed as to the purpose of the study, risks and benefits associated with participation. No investigator may involve a human being as a subject in research unless the investigator has obtained informed consent of the subject or the subject's legally authorized representative. Specific guidelines under §46.116 and §46.117 apply.

Section 7. Human Subjects Review Board

A. Metropolitan State University Human Subjects Review Board (HSRB) is established in accordance with Federal policy §46.102(g).

1. The membership of this board shall include at least five members, with varying qualifications to promote complete and adequate review of research activities, involving human subjects, conducted by the university. This includes research experience and expertise; diversity of gender, cultural heritage, and ethnicity; and sensitivity to issues such as community attitudes. A board with this makeup of members is necessary to safeguard the rights and welfare of human subjects and to promote respect for the HSRB's advice and counsel. In addition, board members will include:
 - a. an academic administrator;
 - b. at least one faculty member representing each college/school/unit, selected by the IFO.
 - c. at least one member who is not otherwise affiliated with the institution and is not part of the immediate family of a person who is affiliated with the institution.
2. To build and maintain expertise, HSRB members are encouraged to serve for a minimum of three years. In order to establish a common knowledge base for new members and all members to remain current with federal regulations and best practices, the HSRB will provide additional human subjects protection training to all members.

Rotation of new membership will stagger such that the majority of the members have at least one year experience serving on the HSRB.

3. The board's responsibilities shall be as follows:
 - a. develop and update policies and procedures for the protection of human subjects and the human subjects review process;
 - b. determine the status of exempt and non-exempt research proposals (as provided in §46.101) and provide HSRB review of all non-exempt proposals;
 - c. review research procedures affecting human subjects and make recommendations to the investigator as specified in §46.109;
 - d. conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year as provided in §46.109(e);
 - e. investigate allegations of mistreatment of human subjects; and
 - f. keep written records of HSRB activities as specified in §46.115.

Section 8. Review Categories

A. **Excluded Activities.** Activities excluded from review are those which:

1. Are not research activities, or
2. Are research activities that:
 - a. Do not involve human subjects,

- b. Do not use records gathered on human subjects, and
 - c. Do not involve human genetic material, human tissue or bodily fluids.
3. Examples of excluded activities:
- a. Journalistic work
 - b. Searches of existing literature
 - c. Quality assurance activities or evaluation projects designed for self-improvement or program evaluation, not meant to contribute to "generalizable" knowledge
 - d. Research activities, conducted by University personnel and intended for internal use only, which are designed to assess, evaluate or otherwise examine:
 - i. University courses, services, and programs (such Instruction Improvement Questionnaires);
 - ii. Procedures for obtaining benefits or services at the University;
 - iii. Possible changes in or alternatives to services, programs or procedures; or
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs.

Excluded activities do not need to be submitted to the HSRB for review. It is expected nonetheless that appropriate measures will be taken to preserve subjects' anonymity and/or confidentiality and that subjects will be informed that their participation is voluntary and no coercive strategies will be used in order to gain subjects' compliance.

B. Exempt Activities. Exempt research activities must be submitted for review by the HSRB using the Exempt Review Form. Exempt activities are research activities that involve minimal risk and fall under one of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
 - a. research on regular and special education instructional strategies; or
 - b. research on the effectiveness of, or the comparison among, instructional techniques, curricula or classroom management methods.
2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly through identifiers linked to the subjects.
3. Research activities that (1) are conducted within an established University course, (2) are directed solely toward the learning of research methodology and procedures, and (3) only involve human subjects who are registered members of the course. Capstone, thesis, or other research activities that are conducted beyond the boundaries of the supervisory classroom environment and involve human subjects who are not registered members of the course are subject to Exempt, Expedited or Full review by the HSRB.

Section 9. Human Subjects Review Board (HSRB) Review Procedures

A. Proposals involving research on human subjects are to be submitted to the HSRB in accordance with policies and procedures established by the HSRB and Federal Regulation

(Title 45 Part 46). Data collection may not begin until full HSRB approval has been obtained. The HSRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

- B. Upon receipt of a proposal, the HSRB chair will determine whether the proposal requires Exempt, Expedited, or Full review (§46.110).
 - 1. Exempt and Expedited reviews are carried out by the HSRB chair or by one or more experienced reviewers designated by the chair from among members of the HSRB.
 - 2. The HSRB member(s) conducting the Exempt or Expedited review may exercise all of the authorities of the HSRB except that the reviewer(s) may not disapprove the research proposal. The reviewer(s) shall refer any research protocol that might have been disapproved to the full HSRB for review. The reviewer(s) may also refer other research proposals to the full HSRB whenever it is believed that a full review is warranted.
 - 3. When the Exempt or Expedited review procedure is used, the HSRB chair shall inform HSRB members of research proposals that have been approved under this procedure.
 - 4. Any member of the HSRB may request that a research proposal that has been approved under the expedited procedure be reviewed by the HSRB in accordance with non-expedited procedures. A majority vote of the members shall decide the issue.
- C. The HSRB will meet at regular intervals to assure timely review of research proposals.
- D. Action of the HSRB will be recorded on the approval form, with one copy returned to the investigator and one copy placed in a permanent file under the supervision of the HSRB chair.
- E. The HSRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have the authority to observe or have a third party observe the consent process and the research.

Section 10. Criteria for HSRB approval of research

- A. In order to approve research covered by this policy the HSRB shall determine that all of the following requirements are satisfied:
 - 1. Risks to subjects are minimized as specified in §46.111(a)(1).
 - 2. Risks to subjects are reasonable in relation to anticipated benefits as specified in §46.111(a)(2).
 - 3. Selection of subjects is equitable as specified in §46.111(a)(3).
 - 4. Informed consent will be sought from each prospective subject or his/her legally authorized representative, in accordance with, and to the extent required by §46.117.

5. Informed consent is appropriately documented, in accordance with, and to the extent required by §46.117.
 6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- B. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Section 11. Suspension or termination of HSRB approval of research

The HSRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HSRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the HSRB's action and shall be reported promptly to the investigator and the Provost and Vice President for Academic Affairs.

Section 12. Review

This procedure will be reviewed by the HSRB and the Provost and Vice President for Academic Affairs as needed.

Section 13. Signatures

Issued on this 9th day of March 2010.



William J. Lowe, Provost and Vice President for Academic Affairs



Sue K. Hammersmith, President