BOARD OF REGENTS POLICY:
Research Involving Human Participants

SECTION I. SCOPE.

This policy governs all research involving human participants conducted at the University of Minnesota (University) or conducted by University faculty, staff, or student researchers.

SECTION II. GUIDING PRINCIPLES.

The University is dedicated to meeting, upholding, and exceeding the highest ethical standards in research practices involving human participants. The University holds each individual involved in research with human participants accountable for adherence to these standards. Essential to the research enterprise is preserving the trust of research participants. Each researcher has a duty to maintain that trust and to protect participant well-being. Individuals who make the gift of consenting to volunteer as research participants trust the University to protect them from harm and to respect their freely given, informed consent to participate in research. All involved in conducting research must ensure that research is conducted ethically and in compliance with University policies and procedures.

SECTION III. COMPLIANCE WITH FEDERAL CODE.

Subd. 1. Roles.
The federal government requires the University to designate the Institutional Review Board (IRB) to ensure that research covered under this policy meets federal requirements. The president or delegate is responsible for overseeing the IRB. University officials may not approve research covered under this policy if it has not been approved by the IRB. However, University officials are authorized to decline to conduct research previously approved by the IRB.

Subd. 2. Compliance with Federal Regulations.
All research subject to this policy shall be conducted in accordance with federal regulations, including, but not limited to, the Department of Health and Human Services' *Protection of Human Subjects* 45 Code of Federal Regulations (CFR) 46, and Food and Drug Administration regulations to protect human subjects, 21 CFR 50, 56, 312, 812.

SECTION IV. COMPLIANCE PROVISIONS.

Subd. 1. Appointments.
The president or delegate shall appoint members of the IRB in accordance with federal regulations.

Subd. 2. Responsibilities of the IRB.
In conjunction with the president or delegate, the IRB and its staff shall provide assurance that all University faculty, staff, and student researchers comply with applicable federal regulations and guidelines. The IRB also shall:

(a) review and approve, require modifications to, or disapprove all research covered under this policy;
(b) monitor and conduct continuing review of research in accordance with applicable regulation; and
(c) report to appropriate University and federal government officials:
    (1) any unanticipated problems involving risks to participants or serious or continuing noncompliance with IRB requirements; and
    (2) any suspension or termination of IRB approval of research.

Subd. 3. Other Responsible Parties.
It is the responsibility of the president or delegate and each principal investigator to implement decisions of the IRB.

Subd. 4. Authorities of the IRB.
The IRB is authorized to:

(a) inspect research facilities;
(b) obtain records and other relevant information relating to the use of human participants in research;
(c) observe the consent process or conduct of research directly or through third parties;
(d) suspend or terminate research not conducted in accordance with the IRB's requirements or research associated with unexpected serious harm to participants;
(e) oversee research at other organizations pursuant to appropriate inter-institutional agreements; and
(f) take other actions as necessary to ensure compliance with federal guidelines and regulations, other applicable federal and state law, Board of Regents policies, and administrative policies and procedures.

Subd. 5. Administrative Policies.
The IRB, with responsible oversight by the president or delegate, shall maintain appropriate administrative policies and procedures to implement this policy. See https://research.umn.edu/units/irb/toolkit-library/overview-0.

REVISION HISTORY

Adopted: July 8, 1994
Amended: November 12, 2004; December 14, 2018
Last Comprehensive Review: 2018
Supersedes: Use of Human Subjects in Research dated July 10, 1987.