



UNIVERSITY OF MINNESOTA
BOARD OF REGENTS POLICY

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Academic

RESEARCH INVOLVING HUMAN SUBJECTS

Adopted: July 8, 1994

Amended: November 12, 2004

Supersedes: (see end of policy)

RESEARCH INVOLVING HUMAN SUBJECTS

SECTION I. SCOPE.

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

SECTION II. 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' *Guidelines for Protection of Human Research 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 III. 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 at intervals of at least once annually; and
- (c) report to appropriate University and federal government officials:



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- (1) any unanticipated problems involving risks to subjects 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 subjects 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 subjects;
- (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.