MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges AREA: Administrative

SUBJECT: Human Subjects Research	POLICY NO. 0007		
APPROVED BY: Kathleen H. Goeppinger, PhD Kathleen H. Goeppinger, Ph.D. President and CEO	ISSUE DATE	SUPERSEDES 12/96	PAGES
	4-2-25		5

PURPOSE: To establish the means by which institutional measures are designed to ensure the safety and welfare of human research subjects.

POLICY: It is the policy of Midwestern University that no research involving human subjects shall be conducted as an activity or in association with any educational program, health care, or other activities under the auspices of MWU until approved by the Institutional Review Board. Approved research projects shall be suspended or terminated by the responsible investigator or upon direction of the chairperson of the Institutional Review Board when a bona fide question is raised concerning unknown or unsuspected risks to human subjects or when departure from research procedures prescribed to protect human subjects occurs until review and action by the committee has been completed.

Research involving human subjects, conducted at Midwestern University and its affiliates, must be reviewed and/or approved by the MWU Institutional Review Board (IRB). This review is required of all such research without qualification as to source of funds. Review by the MWU IRB may also be required of research carried out under the sponsorship of an institution other than MWU but which is performed on the MWU premises, even if the research activities have been approved by the IRB at that institution or elsewhere.

Any individual intending to conduct research involving human subjects, whether or not supported by a grant, contract or fellowship from any public or private agency, must submit a formal application to the IRB. If a grant or contract is involved, this submission should occur sufficiently in advance of the due date of the application in order to allow time for the review process, should it be deemed necessary.

Activities within the scope of the IRB's responsibilities include *research*, development and related activities which would normally be construed as biological, behavioral or psychological investigations involving *human subjects*.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:
(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.,* the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(5) Informed consent will be appropriately documented or appropriately waived.

(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.

(8) For purposes of conducting the limited IRB review, the IRB need not make the determinations at paragraphs (1) through (7) of this section, and shall make the determination that if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

In all activities involving human subjects research, regardless of the type of review or qualification for an exemption, informed consent must be obtained from each participant prior to engaging in the research activity, unless waived by the IRB. In cases where the participant cannot provide consent (children, incapacitated, mentally incompetent, etc.), content must be obtained from the individual's parent, guardian, or legally authorized representative and assent must be obtained from the participant unless the participant is incapacitated or otherwise unable to provide assent. For research projects approved through expected or full board review pathways, investigators must use the MWU-approved informed consent/assent document(s) unless a waiver of documentation of informed consent or a waiver of certain elements of informed consent is granted by the IRB. For exempt research, investigators are required to follow the MWU guidance on study information sheets to convey required information to prospective research participants. According to federal regulations, "informed consent" refers to the knowledgeable agreement of an individual or a legally qualified representative whereby he or she exercises free choice to participate in a study without any undue inducement or any element of force, fraud, deceit, duress, or other kinds of constraint or coercion. An informed consent document must be written in clear, non-technical language and must include appropriate elements as defined in 45 CFR 46.

APPENDIX I

Institutional Review Board

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The charge to the Institutional Review Board (IRB) is to:

(1) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities for which limited IRB review is a condition of exemption.
(2) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned

in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(3) An IRB shall require documentation of informed consent or may waive documentation.

(4) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(5) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in (5) a.

   a. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
      i. Research eligible for expedited review;
      ii. Research reviewed by the IRB in accordance with the limited IRB review;
      iii. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
         1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
         2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

(6) An IRB shall have authority to observe or have a third party observe the consent process and the research.