THE UNIVERSITY OF MICHIGAN

STANDARD PRACTICE GUIDE

SECTION:	Research	**Number:**	303.5
		Revised:	
SUBJECT:	Policy for Research with Human Participants	**Date Issued:**	3/28/05
		Review Date:	3/28/09
		Attachment(s)	0

APPLIES TO: All Human Research Sponsored by the University, Performed by or Under the Direction of University Faculty, Staff, Students or Other Trainees in Connection with their University Affiliations; or Involving Use of Non-Public Individually Identifiable Information Created or Maintained by the University; in University Facilities or Using University Resources

ISSUED BY: Office of the Vice President for Research

All human research conducted by members of the University community, using University facilities or resources, or involving use or disclosure of identifiable private information created or maintained by the University will be guided by the ethical principles of the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report") and performed in compliance with applicable federal and state law.

The University has established a Human Research Participant Protection Program (the "HRPPP"), an integrated system of institutional review boards, other review units, oversight functions, and educational and quality assurance activities that together seek to assure the rights and welfare of human subjects participating in biomedical and behavioral research and promote excellence in all aspects of human subject research. The HRPPP not only promotes compliance with relevant laws, regulations and professional and ethical standards at all levels, it addresses the needs and concerns of researchers and enhances support of their endeavors.

The Vice President for Research exercises general executive responsibility for the research programs of the University and in that role has implemented the HRPPP. This systematic and comprehensive program's integrated components include:

1. Establishment and maintenance of institutional review boards (IRBs) and other review bodies to review and oversee human subjects research and ensure the protection of research participants.
2. Adoption and enforcement of written policies and procedures governing the conduct of human subjects research designed to promote institutional and individual compliance with applicable legal and ethical standards.
3. Institution of educational programs to ensure that members of the research community responsible for human subjects research, including investigators, research staff, and IRB members and staff, understand the legal and ethical standards applicable to human subjects research.
4. Continuous quality improvement initiatives including periodic review of the program's scope and resources dedicated to its implementation; establishment of an Office of Research Compliance and Review to carry out quality assurance functions such as compliance monitoring; appointment of interdisciplinary committees to

facilitate stakeholder communications and input into program goals and operations; and pursuit and maintenance of external accreditation.

At a minimum, all human subjects research performed at the University of Michigan or using its resources will meet the following requirements:

Respect for Persons

- Research protocols must say how subjects will be recruited.
- Subjects must freely agree to participate after receiving complete information about the research and its risks, potential benefits and alternatives.
- Subjects must fully understand their rights including the right to discontinue at any time without loss of otherwise available benefits.
- Vulnerable populations (fetuses, children, prisoners, those without decisional capacity, and those with economic or educational vulnerability) must receive special consideration and protection.

Minimizing Risks and Avoiding Unreasonable Risks

- Research may not expose subjects to unreasonable risk of harm (whether physical, psychological, social, legal or economic in nature).
- The probability and magnitude of possible harm must be reasonable in relation to the anticipated direct or indirect benefits of participation in any research project.
- Identifiable risks that practicably could be avoided without undermining legitimate research objectives must be eliminated.
- Sound research designs that minimize risks and maximize benefits of participation must be used.

Equitable Recruitment and Selection of Subjects

- Research protocols must promote equitable recruitment and selection of subjects, as applicable, with the overall goal of ensuring fair distribution of the burdens and benefits of research. Subjects should be selected for participation for reasons directly related to the questions under study.
- Subjects must not be induced to participate in research projects by means or under circumstances that may overcome the voluntary nature of their participation. Enrollment into a study may never be the product of coercion or undue influence.

Investigator Qualifications and Responsibilities

- Research must be performed or closely supervised by individuals qualified by training and/or experience to minimize risks and otherwise protect subjects. When research is performed by students, supervising faculty members are responsible to ensure that the students are qualified to conduct the research and to safeguard subject rights and welfare.
- Primary responsibility for research with human subjects is vested in the principal investigator conducting a study. This includes responsibility to comply with the laws, regulations, and institutional policies that regulate research. Others engaged in the conduct of the research such as co-investigators and research staff share this responsibility.
- Investigators must follow IRB standard operating procedures for initial submission and approval of proposals, continuing review, and adverse event reporting. Investigators are responsible for informing IRBs of existing knowledge of any risks involved in participating in a study at the time of initial review and for apprising IRBs of any new risks identified during the course of the study.
- Investigators must explain to subjects, prior to their participation in research projects, the objectives of the research, the procedures to be followed, the risks and potential benefits of

participation, and alternatives to participation (where any form of therapy is involved); as well as funding sources and conflicts of interest, where applicable. Individuals may participate as a subject only after voluntarily consenting to participation and must be made aware of their right to withdraw without risking benefits or services to which they otherwise would be entitled. In addition, in most cases, investigators will obtain the assent of subjects, such as minors or mentally incapacitated individuals, before participation. Investigators are responsible for ascertaining that subjects consenting or assenting to research actually comprehend the information provided to them before enrolling them in studies and that subjects are aware of their right to ask questions about the research before, during and after participation. IRBs may waive some of these consent requirements only in limited circumstances.

- Investigators must respect the privacy of subjects participating in their protocols and implement safeguards to protect the confidentiality of data gathered for the research.

Institutional Review Boards

- The University's institutional review boards are authorized to review and to approve, approve with stipulations, or disapprove any research involving human subjects in accord with their own standard operating procedures and applicable institutional policies.
- No human research may be conducted without IRB approval or notification of exemption.
- The University's institutional review boards have the authority to suspend a study or terminate approval of a previously approved study.
- Board membership will meet applicable regulatory standards. Members will appropriately represent the varying perspectives of subjects, investigators, and the community at large. The IRBs will solicit advice from external consultants as needed to ensure appropriate expertise on the boards and represent the views of particular subject populations. IRB members will not participate in the approval of projects in which they are involved or otherwise have a conflicting interest.

Attachments/References:

Belmont Report http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
Human Research Participant Protection Program – Operations Manual [Not yet available]
Glossary [Not yet available]