

Michigan State University Human Research Protection Program	
<i>Subject:</i> Special Considerations	
<i>Sub-Topic:</i> Student Classroom Research	
<i>Section:</i> 6-9-A	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by:</i> IRB, URC, UGC, MSU Legal Counsel	<i>Approved by:</i> Vice President of Research and Graduate Studies, 3-3-2005
<i>Related Sections:</i> 6-4	

In some courses students collect data by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. Some of the methods involve human subjects, and in some instances subjects may be placed at risk. For this reason, student research projects involving human subjects should be reviewed and approved prior to initiation of the research project to assure that the rights and welfare of human subjects are protected. Students also need to learn the principles and policies governing research involving human subjects as a part of instruction in research methods.

Course instructors have primary responsibility for assuring that the rights and welfare of human subjects are not violated. This responsibility includes communicating to students the ethical principles for the protection of human subjects. It also includes reviewing student research protocols and monitoring research activities and reports of findings to assure that human subjects are protected. The course instructor should review Sections 3-5 below to determine if the Michigan State University (MSU) Institutional Review Board (IRB) review is required.

1. Ethical Principles for the Protection of Human Subjects of Research

- 1.1. Every person has the right to determine what shall be done to him or her, what activities he or she shall engage in, and what risks he or she will take. Consequently, research on human subjects cannot be carried out without the subjects' competent, voluntary and informed consent.
- 1.2. No person should be placed at risk as a subject of research unless the risks are reasonable in relation to the anticipated benefits of the research.
- 1.3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and should not impose inequitable risks and burdens on any segment of society.
- 1.4. Special consideration and protection should be given in research to persons who may lack full capacity to secure their own rights and interests, due to age, mental capacity, involuntary custody, cultural barriers or other special circumstances.

2. Definitions

- 2.1. *Student Research* means any observation or intervention by a student as part of a course which is designed to develop or contribute to student learning, and for which publication of findings outside class will not take place.
- 2.2. "*Human Subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." 45 CFR 46.102(f)
- 2.3. *Student Researcher* means any student enrolled in a course at Michigan State University who conducts research on human subjects as an assignment or project in the course, excluding master's or doctoral theses research reviewed under established MSU IRB procedures.
- 2.4. "*Minimal risk* means that the probability and magnitude of 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." 45 CFR 46.102(i)
- 2.5. "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." 45 CFR 46.102(d)

3. Responsibility of Instructors

- 3.1. Instructors of courses in which students do research involving human subjects are responsible for informing students of the ethical principles for the protection of the human subjects of research and applicable policies and procedures.
- 3.2. Instructors of courses in which students do research involving human subjects are responsible for prior review of that research in accordance with these policies and procedures.
- 3.3. The instructor is responsible to assess whether risk is more than minimal as defined in 2.4. If there is any question or doubt about the degree of risk posed by the research and if there is any possibility of more than minimal risk, the protocol must be reviewed under Section 5 below.

4. Instructor Review of Student Classroom Research

- 4.1. If student classroom research involves passive observation of public behavior, poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, instructors shall review and approve the research. Informed consent of subjects is not required. Examples of such research are:

- 1) observation of public behavior except where it is recorded in such a way that the subject can be identified directly or by identifiers linked to the subject and the subject's responses, if they became known, could place the subject at risk of legal liability or financial loss, or deals with sensitive aspects of behavior or use of alcohol.
 - 2) research involving the collection or study of existing data, documents, records or specimens, if they are publicly available or if they are recorded in such a manner that subjects cannot be identified.
 - 3) observation in established or commonly accepted educational settings.
- 4.2. If student classroom research involves intervention but poses no more than minimal risk, the course instructor will be responsible for the review and approval of the research and informed consent of subjects is required. If the research involves more than minimal risk, it must be reviewed by an MSU IRB as described in Section 5.
- 4.2.1. The instructor must review and approve the procedures for obtaining informed consent and assure that they meet the requirements in Section 6-4, "Informed Consent", of the HRP Manual prior to their use by student researchers.
 - 4.2.1.1. The consent form should contain all required elements of consent and be documented appropriately or all requirements of the waiver of consent and/or documentation should be documented and satisfied. *See 45 CFR 46.116 & 45 CFR 46.117 for requirements.*
 - 4.2.2. The instructor must review and approve the instruments, methods and procedures of the research protocol in their final form prior to their use by student researchers.
 - 4.2.3. The instructor must keep a record for at least one calendar year of research protocols which includes the research project title, the student researchers' names and the date of the instructor's review and approval.
 - 4.2.4. Examples of research which may be approved by the procedures described in this section are:
 - 1) research conducted in established or commonly accepted educational settings involving normal educational practices
 - 2) research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information is recorded in such a manner that the subjects cannot be identified directly or through identifiers linked to the subject
 - 3) research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not stress the subjects;

- 4) research involving survey or interview procedures except where responses are recorded in such a way that the subjects can be identified directly or through identifiers linked to the subject and the subjects' responses, if they became known, could place the subject at risk of liability or financial loss, or deals with a sensitive aspect of behavior or alcohol use;
- 5) moderate exercise by healthy volunteers;
- 6) recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.

5. IRB Review of Student Research

If IRB review is required, all IRB policies and procedures are applicable. The research protocol must be submitted to and approved by an MSU IRB prior to any data collection activity if:

- 5.1. Student classroom research involves more than minimal risk.
- 5.2. If at the conception of the student classroom research project, the instructor is aware that the data gathered by the student researchers will be used to produce generalizable knowledge (publications, theses, dissertations).

6. IRB Review of Existing Data from Student Classroom Research

- 6.1. If an individual would like to use the data collected under this student classroom research policy (i.e., approved by the instructor but not by an MSU IRB) for generalization (e.g., publication, theses, dissertations), an initial application must be submitted to the IRB for review and approval.
 - 6.1.1. For projects only using data previously collected under the student classroom researcher policy, the project should be submitted to the IRB under sub-category four in the Exempt review category or sub-category five under the Expedited review category.
 - 6.1.2. The application must include a statement that the instructor approved the project for human subject protection issues. The consent process should be explained and the consent form attached.
 - 6.1.3. The IRB reviewer(s) will determine if the human subject review and procedures were adequately administered by the instructor.
 - 6.1.4. If the project also involves prospective data collection, other categories of review may apply and IRB reviewer(s) may require additional informed consent procedures to be approved by the IRB.