The federal regulations for the protection of human research subjects define “research” as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102(d). In some courses students collect data from human subjects by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. For those student classroom activities that do not meet the federal definition “research” because they are not designed to develop or contribute to generalizable knowledge, Institutional Review Board (IRB) review is not required. In these instances, the instructors are responsible for assuring that human subjects are protected. However, if such activities meet the definition of human subject research (or a clinical investigation) involving human subjects, the activity must be reviewed and approved by the IRB prior to initiation of the activity. See the Human Research Protection Program (HRPP) Manual 4-3, “Determination of Human Subject Research” for definitions and requirements.

If at the conception of the student classroom activity the instructor or student is aware or expects that the data gathered by the student will be used to develop or contribute to generalizable knowledge (e.g., theses, dissertations), the activity must be reviewed and approved by an MSU IRB prior to initiation. Failure to obtain IRB approval is noncompliance. Such noncompliance will be reviewed pursuant to HRPP Manual 9-1 “Noncompliance.”

If a student collects data for non-research purposes and would subsequently like to use the data for research, IRB review may be required. The instructor or student should Contact the IRB to determine if IRB review is required. When an IRB application is required, it should include an explanation of how the data were collected and why IRB approval was not sought prior to data collection. When appropriate, the consent process should be explained and a consent form attached.

When classroom activities not subject to IRB review are undertaken, instructors have primary responsibility for assuring that the rights and welfare of human subjects are protected. To fulfill this responsibility, it is recommended that instructors communicate to students the ethical principles for the protection of human subjects, review student
classroom activities involving humans, and monitor classroom activities and reports of findings to assure that human subjects are protected.

The following sections are provided as guidance for instructors in reviewing such activities that do not require IRB review. It is ultimately the instructors' purview to allow the student classroom activities involving research methodologies to occur as part of the coursework.

Ethical Principles for the Protection of Human Subjects

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, student classroom activities that involve research methodologies on human subjects cannot be carried out without the subjects' competent, voluntary, and informed consent.

2. No person should be placed at risk as a subject of the student classroom activity that involves research methodologies unless the risks are reasonable in relation to the anticipated benefits of the activity.

3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the student classroom activity involving research methodologies and should not impose inequitable risks and burdens on any segment of society.

4. Special consideration and protection should be given in student classroom activities that involve research methodologies 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.

Recommendations for Instructor Review

1. If student classroom activities involving research methodologies involve passive observation of public behavior or analysis of existing data, instructors should review and monitor the activity and informed consent of subjects may not necessarily be required.

2. If student classroom research involving research methodologies involves intervention, the instructor will be responsible for the review and monitoring of the activity and informed consent of subjects (and in the case of children, parental permission) should be required.

3. The instructor should review and monitor the procedures for obtaining informed consent and assure that they meet the requirements in HRPP Manual 6-4 “Informed Consent” prior to their use by students.

4. The consent form should contain all 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 and 45 CFR 46.117 for requirements.

5. The instructor should review and approve the instruments, methods, and procedures in their final form prior to their use by the students.
6. The instructor should keep a record for at least one calendar year of student classroom activities involving research methodologies which includes the project title, the students’ names, and the date of the instructor's review. This is encouraged to address questions that may arise to whether an activity required IRB review.

7. It is recommended that instructors utilize the [MSU Human Research Protection Manual](#).