

**UNIVERSITY OF LOUISIANA AT MONROE
POLICIES AND PROCEDURES MEMORANDUM**

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<i>Title:</i>	Guidelines for Class Projects
<i>Effective Date:</i>	01/02/2013
<i>Update Responsibility:</i>	Academic Affairs
<i>Update Date:</i>	None
<i>Cancellation Date:</i>	None

1) PURPOSE/PREAMBLE

These guidelines are intended to assist The University of Louisiana at Monroe investigators with determining which class projects meet the definition of research and require review by the University's Institutional Review Board (IRB). The University IRB is guided by 45 CFR 46 (Common Rule) which defines research as "a systematic investigation designed to develop or contribute to generalizable knowledge". The IRB distinguishes between student research conducted in a classroom designed for students to "learn how to" conduct research and research conducted to add to generalizable knowledge.

2) DEFINITIONS

- a. Research means a systematic investigation 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 supported or funded under a program, which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.
- b. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
- c. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3) PROCEDURES

- a. Class projects that involve systematic collection of data designed with the intent to develop or contribute to generalizable knowledge are considered research. **If the**

researcher plans to use the data to draw general conclusions, inform policy, or generalize findings beyond the classroom (e.g. publication or presentation), the project is considered research and requires IRB review. The intent to contribute to “generalizable knowledge” makes the experiment or data collection research, regardless of publication or presentation.

- b. Class projects that are designed to provide a learning experience in the methods and procedures of research and NOT for the purpose of “developing or contributing to generalizable knowledge” does not meet the federal definition of research and is therefore not subject to IRB review/approval.

The class project does **not** need to be reviewed by the IRB if **all** of the following conditions are satisfied:

1. The project is a class assignment designed for learning purposes only and is not designed to develop or contribute to generalizable knowledge;
2. The project is supervised by a faculty member who has undergone CITI training;
3. The projects primary purpose is to develop student’s research skills;
4. Research does not present more than minimal risk to participants or to student investigator;
5. Research does not include vulnerable populations according to Federal regulations (e.g. children under age 18, prisoners, pregnant women, mentally or physically challenged individuals, etc);
6. Results of the research will never be distributed outside the classroom and/or institutional setting or used for public dissemination;
7. Research data will be collected and recorded in such a manner that subjects are not identified.

All research involving vulnerable populations or sensitive topics must be reviewed and approved by IRB. Also, if the researcher believes that there is a possibility that the collected data will be used in a future research project or presentation then IRB approval should be obtained prior to initiation of the project. If the faculty member supervising the class project has concerns or doubts, he/she should consult with the University’s IRB.

Categories of sensitive topics includes (but is not limited to) information:

- relating to sexual attitudes, preferences, or practices;
- relating to the use of alcohol, drugs, or other addictive products;
- pertaining to illegal conduct;
- that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
- that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- pertaining to an individual's psychological well-being or mental health; and
- pertaining to genetic information or tissue samples.

- c. **Theses, dissertations, and other formal research projects** involving human subjects that are considered research as defined by 45 CFR 46 **always** require review by the IRB.

4) RESPONSIBILITIES

Faculty overseeing class projects are responsible for determining whether the project meets the definition of research.

If the class project meets the definition of research:

- a. The faculty member should meet with the student to prepare the IRB application.

If the class projects does not meet the definition of research:

- a. The faculty member must be fully aware of all aspects of the class project and must ensure that ethical principles are adhered to during the project.
- b. The faculty member must ensure that the project involves minimal risk to subjects.
- c. The faculty member must ensure that the project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.
- d. The faculty member must ensure that the project does not involve vulnerable populations as participants.
- e. The faculty member must ensure that the project involves the voluntary participation of individuals without coercion by the student.
- f. The faculty member must ensure that the data will be collected and recorded in such a manner that subjects are not identified and that all data is destroyed after the class project is complete.
- g. The faculty member must ensure that the results of the project will never be distributed outside the classroom and/or institutional setting or used for public dissemination.
- h. The faculty member must ensure that informed consent is obtained for all class projects.

Note: The IRB is available to give feedback on any proposed class project not meeting the definition of research, even though the IRB would not officially act on the project.