

**INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA**

COURSES INVOLVING STUDENTS' INVESTIGATIONS USING HUMAN SUBJECTS

POLICY: Many departments on campus offer courses that require students to carry out projects involving investigations with human subjects. These activities may or may not need IRB review and approval. The UM IRB has developed a set of guidelines for instructors who teach courses which require students' investigations using human subjects. If students in any class (undergraduate or graduate) are required to carry out a project which requires information to be obtained from human subjects, the instructor of the course must follow the guidelines articulated below. Form IRB-100 must be submitted before the students can start data collection and the IRB must approve or exempt the proposal.

PROCEDURES:

1. Once per academic year for each course using human subjects (or, given that it might be offered more than once a year, whenever the syllabus of such a course be substantially modified or altered), the instructor must submit an IRB proposal (Form IRB-100, attached hereto) to the IRB for review. This form is also available from the Office of Research and on the website at <http://www.umt.edu/research/irb.htm>.
2. The IRB must approve or exempt the proposal from IRB oversight before students can begin data collection.
3. Once the IRB has approved or exempted the proposal, it is the responsibility of the class instructor to evaluate the ethical soundness and risk level of each student's research project before the student can begin data collection.
4. The proposal submitted by the instructor to the IRB should include a description of the system the instructor will use to evaluate the level of risk to the subjects and ethical soundness of each student's research project. That is, the proposal should include a detailed summary of the process through which the instructor will:
 - (a) educate the students concerning level of risk to the subjects (e.g., of physical injury in a class on methods of evaluation of athletic performance; or, e.g., of injury to self esteem in a class on methods of interview) and relevant ethical guidelines by means of readings, class lectures, etc.; and

- (b) assess whether students' projects are ethically sound and of an acceptably low level of risk of physical, social, and psychological injury by means of, for example, "mock IRB proposals" that students submit to the instructor or class evaluation of each student's proposal, etc.
5. If the predominant focus of the course is to teach research methods, a copy of the class syllabus should be submitted to the IRB. This syllabus should indicate that ethical issues will be discussed in class, and should list the written sources (e.g., textbook, published ethical guidelines) which will be used to educate students concerning ethical issues.
 6. The IRB Chair may review and Exempt or give Administrative Approval to most proposals for courses which require student investigations with human subjects. If, in the Chair's opinion, the nature of the students' projects may involve more than minimal risk to the subjects or will be covered by paragraph #7 below, review by the entire IRB will be required.
 7. Any student project that involves either (a) vulnerable populations, or (b) more than minimal risk must be submitted as a separate proposal to the IRB. That student must await approval from the IRB before commencing data collection. Therefore, it is the instructor's responsibility to ensure either that (a) student projects do not deal with vulnerable populations or entail more than minimal risk, or (b) any student project that does involve vulnerable populations or more than minimal risk must come before the IRB for review, just as any such research project would.

The following was taken from 45 CFR, Part 46 - PROTECTION OF HUMAN SUBJECTS to provide guidance for determining if a project is "Exempt" or not.

Educational tests, survey procedures or observations of public behavior are not exempt if "...any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability or reputation."

"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. ...[S]ome demonstration and service programs may include research activities."

APPROVED:  DATE: 11/12/03
Chair, UM IRB

For Internal
Use Only

Proposal # _____
Form IRB-100
(11/03)

The University of Montana
Institutional Review Board (IRB)
Research Methods Course Form

Submit one completed copy of this Approval Form, including any required attachments, for each course. The IRB meets monthly to evaluate proposals, and approval is granted for one academic year. See IRB Guidelines and Procedures for details.

Instructor of Course: _____ Dept.: _____ Phone: _____

Signature: _____ Date: _____

E-mail: _____

Course Number and Title: _____

Number of Sections: _____ Semester(s) Requesting Approval: _____
(Approval is given for only 1 year)

Course
Description: _____

Submit the following:

1. Summary of methods by which the instructor will educate the students concerning level of risk and relevant ethical issues. (Attach course syllabus.)
2. Summary of the process the instructor will use to assess whether the students' projects are ethically sound, of acceptable low level risk of physical, social, and psychological injury, and do not involve vulnerable populations. Include topics typically selected by your students.
3. Written sources (e.g. textbooks, published ethical guidelines) that will be used to educate students concerning ethical issues, level of risk, and other relevant issues.

For IRB Use Only

IRB Review and Determination

_____ Approval to instructor to oversee projects that involve minimal risk and that do not involve vulnerable populations; usually these would be Exempt from UM IRB review. (Any student project that involves (a) vulnerable populations, or (b) more than minimal risk must be submitted as a separate proposal to the IRB. That student must await approval from the IRB before commencing data collection.)

_____ Conditional Approval (see attached memo)

_____ Resubmit Proposal

_____ Disapprove

Signature/IRB Chair _____ Date: _____