

The University of Mississippi

WAIVER OF IRB APPLICATION FOR CLASS PROJECTS

Summary/Purpose: To offer instructors who assign class projects using humans (who are not enrolled in the class) as subjects an alternative to requiring each student to submit an IRB application.

It is the University of Mississippi IRB's policy to review all research conducted by faculty, staff, and students. The IRB must determine if studies meet the Code of Federal Regulations definition of "Research," which requires a formal IRB application. Many class-assigned projects using humans as subjects do not meet the criteria in the federal definition of research (i.e., "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*"). In some of these cases, classroom projects may not require an IRB application.

To minimize administrative burdens on instructors and students, the IRB offers instructors an alternative to requiring each student to submit an IRB application, provided that both **NONE** of the conditions in **A** below are met and that the instructor agrees to fulfill **ALL** responsibilities in **B**.

A. Waiver of IRB Application for Class Projects is prohibited when the study meets one or more of the following conditions:

1. Publication or presentation outside of the University of Mississippi. Data obtained from this class project CANNOT be used for publication, presentation at a professional meeting, or used in thesis/dissertation research.

2. Use of vulnerable populations or participants under the age of 18, except on a case by case basis determined by the IRB Executive Committee. The project(s) cannot involve participants under 18, prisoners, or persons lacking the capacity to give informed consent (e.g., mentally disabled, under the influence of drugs or alcohol, etc.). **Exception for participants under 18:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies, or research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.

3. Risk more than "Minimal Risk." "Minimal risk" is when "the probability and magnitude of harm or discomfort 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." [45CFR 46.102(i)] Videotaping may exceed minimal risk and will be evaluated on a case by case basis.

4. Use of deception. The class project may not include deception of any kind (e.g., omission of information, misleading instructions, etc.). All subjects must be fully informed of the nature of the project, its risks and benefits, and give voluntary consent to participate (when applicable).

B. Instructors granted a class project waiver must accept primary responsibility for ensuring the rights and welfare of the human subjects. Instructors must:

1. Train students in the proper conduct of research and the protection of human subjects.

To supplement classroom instruction on research ethics, the IRB requires instructors to have students complete Human Subjects Ethics Quiz after they study the “What is Human Subjects Research?” education materials. Instructors must require 100% correct quiz answers. Instructors must complete the CITI Basic Course.

2. Review *Student Class Project Applications* and determine if each project qualifies for a waiver. The IRB does not review these applications. Instructors are responsible for keeping all paperwork associated with the course for a period of one calendar year.

3. Ensure that students get informed consent from subjects and assent from children when applicable. See the IRB Forms page for sample consent and assent forms for class projects.

4. Review all methods and instruments used in each project.

5. Document that students receive permission to conduct research at institutions/places other than The University of Mississippi. This includes written permission from someone authorized to permit the research, for example: letters from school authorities, pharmacy managers, or store owners.

Procedures

1. Instructor submits *Request for Class Project Waiver of IRB Application* to IRB office for review.

2. IRB reviews, requests clarification (if necessary), and issues approval or denial notice.

3. Students submit *Student Class Project Application* to instructor, who reviews for waiver compatibility and retains for one year.

Group or individual student class projects that do not meet waiver criteria cannot be conducted until either the standard IRB *Application to Conduct Research with Human Subjects* or the *Screening/Abbreviated IRB Application*, as appropriate for the particular study, is submitted and approved by the IRB.