

Class-based assignments or activities involving human subjects

The policy below establishes the procedures for course instructors to follow for class assignments that involve human subjects when these activities are not considered research according to the definition given in the *Final Common Rule*

- 1) If the following conditions are satisfied, the class-based assignment or activities are not considered research according to the definition provided by the *Final Common Rule* and are outside the IRB jurisdiction
 - a) The primary purpose is a learning experience in the methods and procedures of research.
 - b) All students in the class use the same type of methods, tools or instruments (e.g., surveys, interview questionnaires) ¹.
 - c) The activities involve no more than minimal risk as defined in the Final Common Rule.
 - d) The activities involve the minimum number of human subjects necessary for them to be meaningful for the learning experience and the teaching goals. This number would typically be smaller than the number needed for research purposes where, for example, statistical considerations are taking into account.
 - e) The projects do not include sensitive topics or vulnerable populations, such as children, prisoners, or pregnant women.
 - f) The data are recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names, or the recorded data will not identify the subjects through their behavior).
 - g) All collected data is kept confidential. The class Instructor is responsible for assuring compliance of this rule.
 - h) The data will not be used beyond the classroom environment. Specifically, the data is only used for evaluation or other class (e.g., a course paper, oral class presentation). The data cannot be published or presented at a conference, colloquium, department colloquium or poster presentation and cannot be disseminated in further research by the student, other class members and/or the instructor.

- 2) The course instructors
 - a) Are responsible for the conduct of projects.
 - b) Must adhere and assure that the guidelines outlined in this document are met.
 - c) Must provide basic training to students on standard research practices to protect the rights and welfare of the human subjects as described by the federal regulations.
 - d) Must submit a form briefly describing
 - i) The class assignments.
 - ii) The course objectives.

¹ See (2g)

- iii) The subject population and recruitment.
 - iv) The methodology.
 - v) The consent process.
 - vi) The provisions for the protection of any identifiable information.
 - e) Must provide a copy of the surveys, interview questionnaires or any other similar instrument used for the project.
 - f) Must provide a copy of the oral or written consent form (based on the template attached to the form).
 - g) If different groups in a class use different types of methods, tools or instruments, a separate form must be submitted for each group.
- 3) If any changes that imply a deviation from the provisions of this policy and the signed form occur, an IRB application must be immediately submitted to the IRB for approval.
 - 4) If any of the conditions stated above is not met, an IRB member (liaison) will conduct and expedite review to determine if the activities are exempted from further IRB review
 - 5) If the activities are deemed not to be exempted from further IRB review, the IRB liaison will conduct and expedite review following the submission of the corresponding IRB application
 - 6) If the expedite review does not result in the approval of the activity, then it will be discussed by the full IRB
 - 7) No data collection activities must be carried out unless the course instructor has acquired "class-assignment" status for the specific course projects, the projects have been exempted from further IRB review or they have been approved by the IRB.