

## When Does a Class Assignment Require IRB Approval?

In support of its teaching and research mission, the University encourages novel and innovative classroom activities. Some faculty design class assignments that involve questionnaires, interviews, or other interactions with individuals, such as those commonly used in research methods courses. Such assignments are also often presented at internal and external research and scholarship conferences. This memo addresses whether and when such assignments should be reviewed by the Institutional Review Board (IRB) to ensure the protection of human subjects.

The purposes of this memo are:

- to clarify when student class assignments fall under the jurisdiction of the Institutional Review Board (IRB); and
- to underscore the obligations of instructors to consider and mitigate potential risks to individuals affected by class assignments even if they are not under the IRB jurisdiction.

NOTE: This memo is meant to clarify the IRB's role in reviewing student class assignments. Independent research projects conducted by students, such as theses, dissertations, honors projects, and independent study projects that collect data through interactions with living people or access to private information **do** fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include an endorsement and acceptance of overall responsibility by a faculty member. Per Boise State policy, undergraduate and graduate students may not serve as principal investigators unless the project is a graduate student's thesis or dissertation; rather students should serve as co-investigators with their faculty mentor as the principal investigator.

### **DEFINITIONS:**

*Research:* A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" 45 CFR 46.102(d).

*Generalizable Knowledge:* Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated). A useful definition of dissemination is that the material will be shared beyond the local setting. Obvious examples of dissemination are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library. Examples that are not dissemination include oral presentation to a departmental group in fulfillment of a university requirement, sharing of

results with an agency that cooperated in information collection, or internal presentation for utilization and review purposes.

## **CLASS ASSIGNMENTS**

Faculty members may design assignments that engage students in interaction with individuals or data about individuals to teach research methods or to help students understand concepts covered by the course. For the most part, they are not intended to create new knowledge or to lead to scholarly publication. Therefore, student class assignments, as a general rule, are not systematic data collection efforts intended to develop or contribute to *generalizable* knowledge and, thus, do not meet the federal regulatory definition of "research" and do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight **unless the project falls into the following exception:**

**EXCEPTION:** When student class assignments are intended to collect information systematically *with the intent to develop or contribute to generalizable* knowledge (e.g., publish the findings, present them at a research conference outside of Boise State), the assignments are, indeed, "research" and do fall under the jurisdiction of the IRB. Instructors wishing to use such assignments must apply to the IRB for review and approval of these assignments before they begin.

The intent to publish, present, or otherwise disseminate the results of the activity is one clear indication that the activity is regulated as research. **If an instructor or student anticipates possibly publishing or presenting results from classroom research exercises, the project then meets the definition of "research" and an IRB application must be submitted PRIOR to initiating the project. The IRB does not give retrospective approval.** Even if the decision to publish or present the results is contingent on study findings (e.g., if the class project goes well, your students will submit their findings to a scholarly journal or present them at a conference outside of Boise State), you must submit an application to the IRB **prior** to data collection.

**NOTE:** If results are presented on campus only (e.g., in the classroom or the BSU Undergraduate Research and Scholarship Conference) IRB review is **not** required. If results are shared **ONLY** with an agency that cooperated in the information collected for internal utilization and review purposes (e.g., Service-Learning projects involving internal program evaluations that will not be shared beyond the agency), IRB review is **not** required.

Student-initiated class assignments that are not subject to IRB oversight include those that:

1. Are conducted solely within the confines of the classroom if they:
  - a. are a general requirement of the course and,
  - b. have the sole purpose of developing the student's skills.
2. Are part of a larger research project that has current BSU IRB approval, and the approved protocol includes student engagement in the specific activities.

## **INSTRUCTOR'S RESPONSIBILITIES**

Although most class assignments are designed as instructive measures and are not the type of activities typically overseen by the IRB, there are instances when the nature of these projects is such that participants could be put at some risk of harm. For example, if a student proposes to ask minors about their safe-sex habits and the minor's responses can be linked to their identities, there is risk of harm if confidentiality is breached. Breach of confidentiality could create emotional stress from the participant, as could the questions themselves as they are of a sensitive nature. While these assignments are still not considered "research" and are not reviewed by the IRB, the instructor is still responsible for minimizing risks to participants in these projects. The IRB strongly encourages instructors to contact the ORC for [guidance](#), and to ensure students are educated about these risks and how to minimize such risks.

The types of student-initiated class projects involving more than minimal risk may include those that:

- Include minors (e.g., persons under the age of 18);
- Target potentially vulnerable individuals (e.g., those whose capacity to freely give consent may be compromised because of socio-economic, educational, or linguistic disadvantage; cognitive impairment; advanced age; or terminal illness);
- Deal with a topic of sensitive or personal nature in a way in which anonymity cannot be sustained and the examination or reporting of participant response or behavior may be potentially stigmatizing or place the participant at more than minimal risk physically, psychologically, socially, or economically or for civil or criminal liability;
- Involve any other type of activity that places the participants at more than minimal risk, considering both the probability and the magnitude of harm.

## **SUMMARY**

Novel and imaginative classroom exercises help students learn and are, therefore, integral to high quality teaching. All teaching assignments, however, must respect the rights and welfare of all individuals involved. Consider the nature and intent of the activity. If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge -- an indication of which is possible publication, presentation, or other dissemination of the data -- then the student classroom assignment is probably research and should be reviewed and approved by the IRB. See the Office of Research Compliance website for applications and forms: <http://www.boisestate.edu/research/compliance/forms.shtml>.

Ask the Office of Research Compliance for guidance when you are unsure. The ORC may be reached by emailing [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu), calling (208) 426-5401, or by writing: Institutional Review Board, Office of Research Compliance, Boise State University, 1910 University Dr., Boise, ID 83725-1138.