

Guidance Document:

Students as Research Subjects: How to Avoid Undue Influence and Coercion

Overview

There is an inherent power differential between students and instructors, faculty members, and teachers who serve as Principal Investigators (PIs) or members of research teams (referred to below as an "instructor/researcher"). No matter how well intentioned the investigator, students may feel compelled to participate in a study, believing that failure to do so will negatively affect their grades or the attitude of the instructor/researcher (and perhaps other students) toward them. For this reason, particular care must be taken when students are used as subjects. Specific steps should be taken to eliminate or reduce the risk of undue influence or coercion by faculty that may affect student participation in research.

Although students often provide a ready source of potential participants, they are not always an appropriate or representative study sample as compared to other subject groups. Attention should be given to whether they are being solicited because they are a convenient and accessible sample, rather than as a representative sample for the research inquiry.

This document provides guidelines to assist investigators who engage in research projects in which students will be asked to be research subjects.

Can I invite students I teach to participate in a study I am conducting?

Yes, however:

- a) The research must present no more than minimal risk to subjects.
- b) Recruitment should be conducted by personnel not involved in instruction, or involve only indirect methods. A faculty instructor, teaching assistants or others involved in course activities or grading should not recruit participants. Other research staff who are not involved in course activities should do so instead. Participants may also be recruited through the posting of IRB-approved flyers/ads, or through IRB approved communications sent out to a larger group (such as mass mailings like emails or letters). Additional guidance on recruiting can be found here: Advertising and Recruitment
- c) Likewise, the consent process should be conducted by a co-Investigator who not involved in grading of course activities as well. This may require bringing in additional study personnel to conduct recruitment and consent procedures. See "third party" information, below.
- d) If the research is conducted within a classroom setting, the instructor should be blinded to the identity of the participants, meaning the instructor does not know who is or is not a participant in the study. To help prevent un-blinding of instructors, data should not be analyzed until final grades have been posted. See example below.



What should I include in my protocol if I want to include my students as potential subjects?

When submitting a study for review and procedures include subjects who are your students, be sure to include details as to how each point above will be addressed in the protocol document. This information will be located throughout the protocol, including the Study Design, Recruitment and Consent sections, the Procedures section and the Data Management section.

What if I want to enroll students in a classroom where I am not the instructor?

Many of the same principals as discussed apply in any classroom setting. Investigators should always be aware of the student/teacher power differential, and work to ensure student subjects are not unduly influenced to participate in a study due to concerns about grades, favoritism, or other factors from this relationship.

What is meant by collection of data by third party?

In studies where the research activities to be undertaken by the students are not part of required class activities, and thus students may choose to participate or not participate, the instructor/researcher should arrange to have the data collected by an independent third party, so that the instructor does not know who participated, and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered.

For example, if the instructor/researcher wants to administer pre- and post- tests to determine the efficacy of a particular curriculum, the necessary consent forms could be obtained, and the tests administered by, a colleague at times when the instructor was not present. A graduate teaching assistant in the class in which the students/subjects are enrolled does not qualify as a third party for collecting data on behalf of the instructor as described above.

What if collecting data by a third party is not feasible?

Some research studies are designed to evaluate or study particular curricular changes or interventions. The use of an experimental curriculum would prevent the instructor/researcher from being absent for all research activities. If conduct of research activities by a third party is not feasible, the IRB requires that the student's written consent for these activities be obtained after grades are entered. While the requirement to obtain Consent for participation in the curriculum itself may be <u>Waived</u>, consent to use students' data, test results, papers written, homework, etc. is still obtained on the basis that this is existing information. Information about students who do not consent to this data use is not analyzed as research data.

For example, use of a particular teaching method throughout the class might not be capable of being structured so that students could opt out. Typically, we ask the instructor/researcher to obtain the subjects' written consent at the beginning of the course concerning the study wherever possible. This



written consent should make clear that the students will have an opportunity to again agree or not to agree (i.e. re-consent) to the inclusion of their data in the instructor's study after the course is finished and grades are entered. By fashioning the student's participation in this manner, we do not place the student in the position of having to either choose to participate or find an alternative course.

What are some practices in research involving students that may require extra attention?

- Use of Extra Credit for Participation. Sometimes participation in the investigator's research is structured as an available extra credit assignment. Even when other means of obtaining extra credit are available, the IRB may not find this is sufficient to overcome the power disparity and the perception of students that participation in the instructor's research is expected, even if not required. If extra credit is offered for research participation, the IRB strongly recommends that a *comparable* alternate assignment is offered to students who do not wish to participate but would like the opportunity to earn extra credit. The additional means of gaining such credits must require a similar level of commitment of time and effort as the research participation.
- Group activities. Group activities that are required as part of the course instruction pose a
 particularly difficult situation because the practicality of a student opting out is very limited. If
 the data is a group project or recording of the group interaction, each student's consent is
 necessary for the use of that data in the research. If one student does not consent, the data may
 be used only if the non-consenting student's data can be effectively excluded. Where this is be
 possible, none of the data can be used.
- Use of student grades and other assessments. In research where the instructor wants access to
 identifiable student academic records, a consent process is required even if the research
 activities conducted in the classroom are conducted by a third party and otherwise fall under an
 exempt category of research. For example, administration of a pre- and post-test by a third
 party which may normally qualify as exempt research under either category 1 or 2 requires the
 provision of an information sheet, but not signed consent. If, however, part of the research also
 includes access to the individual, identifiable student's other grades etc., signed consent from
 each student is necessary.
- Minors. Research involving minors (under 18 years of age) as subjects, (even 17 year old college students) in most instances requires a signed parental permission, as well as the assent/consent of the student.
- Graduate Teaching Assistants. Research conducted by graduate students in a class in which the
 researcher teaches, assists in the class or does any grading are subject to the same restraints
 described above.