

Human Research Protection Program Policies & Procedures



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Version 1.0
Date Effective: 4.20.2010

Background

In some research situations, use of students is integral to the research protocol. This is particularly true of research into teaching methods, curricula and other areas related to the study of teaching and learning. An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is wholly voluntary and based on complete and accurate information.

There has been increasing concern in recent years in the academic community about students participating in research conducted at the institution in which they are enrolled. The primary concern with respect to students is the possibility that, under certain circumstances, they may not feel free to refuse to participate. The student-teacher relationship can raise an issue of volunteer participation. Students may volunteer to participate under the belief that doing so will place them in a favorable situation with faculty or that failure to participate will negatively affect their relationship with faculty.

Oregon Health and Sciences University (OHSU) must weigh its responsibility for the safety of its students against its obligation to respect the choices of students who genuinely and voluntarily wish to participate in research that has been vetted by the OHSU Institutional Review Board as ethically acceptable. Additionally, OHSU must take into account that the risk and burdens of research participation should not necessarily be incurred solely by those individuals outside of the institution.

Scope

This policy defines the standards and parameters for the recruitment of students as research participants for medical, health, social, behavioral and educational research studies conducted at OHSU.

I. Policy

- A. Whenever possible, investigators should avoid using their own students if another population of subjects is equally suited to the research question. Examples include; another class section that is not taught by the investigator, recruitment by another instructor, or blind/coded data collection by an independent third party so research participants cannot be identified to the instructor.
- B. A student may not be compelled to participate in instructor-initiated research as part of a course requirement.
- C. When deception is used, students have the right to full disclosure as soon as possible. Whenever possible, a teaching opportunity in the form of an "educational debriefing" should be employed.

- D. Prior to conducting any research involving students at OHSU, the PI must obtain the approval of Student Health Services.
- E. According to FERPA, investigators generally may not access classroom performance evaluations, grades or information in a student's record without prior written permission from the student, regardless of the access an investigator may have.
- F. When course credit or extra credit is given to students who participate in research as part of a course requirements, students are to be given a non-research alternative for earning an equivalent amount of extra credit. This project should be comparable in terms of: time, effort and educational benefit to participation as a research subject to ensure that students are not being coerced into becoming subjects. Alternatives offered to research participants must have prior OHSU IRB approval.

II. Procedures

A. Requirements for Submission

1. The question in the electronic IRB indicating that OHSU students will be enrolled, must be checked if students are being targeted for enrollment. Not
2. A full description of the type of data that will be requested or accessed must be described in the protocol.
3. Many studies involving students examine educational methods and improvements and may qualify for exemption 1 or 2.
4. Clinical Studies targeting students will require review by Student Health Services. This is done automatically when enrolling "OHSU Students" is indicated in the eIRB application.

B. Investigator Responsibilities:

1. Investigators recruiting students for participation in research should:
 - a. Make sure student participants fully understand they can choose not to participate in the research and their decision will not affect their grade or standing in the class;
 - b. Make sure students participants know that they are allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion.
 - c. Limit the use of extra credit as compensation, extra credit should not significantly increase a student's overall grade. In general it is favorable to give credit if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student; and
 - d. Avoid using class time to recruit or engage students in research.
2. Using Deception in Research
 - a. Students should know something about the rationale for the study, the process of data collection and intent of the researcher.
 - b. In exceptional circumstances, investigators do not have to reveal the full or true purpose of the research to participants until the data collection is complete. However, under these circumstances, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data has been collected.

C. Recruiting student participants

1. All recruitment materials must be submitted to the OHSU IRB for review and approval prior to use.
2. Solicitation of volunteer students for research must be done in a non-coercive manner. To avoid undue influence, subjects should be recruited by a general announcement, central posting or announcement mechanism.

D. Informed Consent

1. Required Language When Recruiting OHSU Students or Employees - *The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course.*
2. Third Party Contact - In addition to being provided with the traditional information and consent forms, the student should also be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process.
3. When Credit is being Awarded - The informed consent process must explicitly state how much extra credit is to be awarded and at what point. Informed consent must indicate how or whether extra credit will be awarded if the student withdraws from the study before completion.

III. Definitions

The **Family Educational Rights and Privacy Act (FERPA)** is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students." Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to (1) School officials with legitimate educational interest; (2) Organizations conducting certain studies for or on behalf of the school; (3) Appropriate officials in cases of health and safety emergencies; and (4) Other parties or under certain conditions so specified in 34 CFR §99.31. (20 U.S.C. §1232g; 34 CFR Part 99).

IV. Authority and Guidance

FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators (1998 Update). <http://www.fda.gov/oc/ohrt/IRBs/toc4.html>.

According to 21 CFR 56.111 there are several requirements that must be fulfilled before the IRB can approve a research protocol.

According to 21 CFR 56.109(a), an IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

According to 21 CFR 312.7(a), a sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.

According to 21 CFR 812.7(d), a sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not represent that an investigational device is safe or effective for the purposes for which it is being investigated.

Family Educational Rights and Privacy Act Regulations (FERPA): 34 CFR 99.31; 20 U.S.C. 1232g; 34 CFR Part 99.