

# II4A-A PR1 Students as Research Participants

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Minor students may be enrolled in research provided that investigators abide by the additional requirements under 45 CFR 46 Part D (see IRB Policy II4D and the related procedures and guidance). Investigators must work with the school districts in which the research is to take place and obtain district approval when required and must also obtain permission from the principals at all targeted schools. Both the district approval and site permission letters must be provided to the IRB with the initial application, or before IRB approval is certified.

Students enrolled in the University of Nevada, Reno (the University) and Truckee Meadows Community College (TMCC) (e.g., undergraduates, graduate students, medical students, residents, fellows) may be recruited for research participation; however, a student may not be required to participate in research without the option of choosing a comparable non-research alternative to fulfill the course requirement.

Students, whether as individuals or groups, should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion in the research study.

## II4A-A1 Recruitment

Recruitment of students as research participants must be designed to minimize the possibility of undue influence. In general, potential participants should be solicited from a broad-base of individuals meeting the conditions for the study, rather than by personal solicitation of specific students.

Strategies to minimize the potential influence of an investigator when recruiting her or his students include recruitment by general announcements, postings or other methods by which interested students initiate contact with the investigator. University policy does not allow the use of sign-up sheets for obtaining information about multiple students, whether posted in a central location or circulated among a group of students. "Sign-up sheets" that consist of a single page are acceptable. To protect student privacy related to their decisions about participation, it is preferable for all students to turn in the sheet whether completed or blank.

When the subjects of research include students who receive instruction directly from the investigator, the investigator must employ recruitment strategies that ensure that participation is voluntary. Some students may volunteer to participate in research in an effort to please a teacher. Students may volunteer for research to earn extra credit when credit is given for participation without equivalent, alternative activities to earn or because they fear that failure to participate will negatively affect their relationship with the teacher-investigator or faculty in general (i.e., by seeming uncooperative or unaware of scholarly research). Students' cultural or religious backgrounds (e.g., requiring deference to authority figures) may also influence their choices.

A student's decision about research participation may not affect (favorably or unfavorably) grades, potential letters of recommendation or other opportunities or decisions made by teacher-investigators; investigators have an obligation to make this clear during both recruitment, consent, permission and assent processes.

Except in unusual circumstances, investigators should not enroll students from their own classes when the research involves greater than minimal risk without the prospect of direct benefit. Such studies should proceed only where the IRB determines that adequate provisions have been made to minimize the possibility of undue influence or coercion, the research is of significant importance and could not be conducted without the enrollment of these students.

## **II4A-A2 Safeguards for Privacy**

Depending on institutional policy, student directory information may be made available for select purposes (see Policy II3D for research involving University and affiliate researchers and guidance II3D GD1 [for external researchers]). In such cases, a letter of support from an individual authorized to speak on behalf of the institution (e.g., department chair, dean) must be submitted with the protocol application or, before approval will be certified.

Additional safeguards may be needed to protect the privacy interests when research participants are students. Classroom conditions may make it difficult for investigators to keep an individual's participation private, which could pose risks to participants, such as when stigma is associated with the condition or question under study or when peer pressure is a component of the research. In such situations, consideration should be given to whether conducting the research off-site or outside of regular school hours may minimize potential risks.

Protecting the confidentiality of research participants' personal information when the participants are students may also present additional challenges. In the informed consent and assent processes, and when obtaining parental permission as applicable, potential participants and their parents or guardians must be told the extent to which personal information and research data may be accessible to parents, teachers or others not directly involved in the research.

In cases where regular classroom activities are also the topic of research, investigators must clarify for potential research participants, and their parents when students are minors, which activities are optional and distinct from required classroom activities that would take place even without the research. When access to students' educational records, such as grades or coursework, is needed for research activities, the requirements of the Family Educational and Rights Privacy Act (FERPA) apply, including when the investigator is the instructor. As the instructor, access to this information is a given but if the instructor plans to use the data for research, she or he has replaced her or his "instructor hat" with an "investigator hat" (See below for FERPA requirements, section II4A3).

## II4A-A2a Family Educational and Rights Privacy Act

Federal regulations provide additional protections for insuring privacy of educational records: the Family Educational and Rights Privacy Act (FERPA). The proposed use of student education records for research must comply with FERPA requirements (see IRB guidance I1D GD5 for Department of Education regulations, and IRB Policy II3D Privacy in Human Subjects Research and guidance II3D GD1 related to use of director information for external researchers). University and affiliate investigators planning to conduct research at external sites must contact each institution in which they will be conducting research to obtain that institution's FERPA policy. Investigators must abide by the FERPA requirements at external institutions, in addition to the requirements of the University and the IRB.

## II4A-A2b Protection of Pupil Rights Amendment

Research\* involving surveys; or psychiatric or psychological examination, testing or treatment with students in elementary and secondary schools must comply with the Protection of Pupil Rights Amendment (PPRA). A summary of PPRA is provided immediately below. Additional information about PPRA is available online at <http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html>

Parental permission (i.e., consent) and minor assent are required and may not be waived or altered for studies involving surveys; or psychiatric or psychological examination, testing or treatment in which the primary purpose is to reveal information concerning one or more of the following:

1. political affiliations;
2. mental or psychological problems potentially embarrassing to the student or her or his family;
3. sex behavior or attitudes;
4. illegal, anti-social, self-incriminating or demeaning behavior;
5. critical appraisals of other individuals with whom the student has close family relationships;
6. legally recognized privileged and analogous relationships, such as those of lawyers, physicians and ministers;
7. religious practices, affiliations, or beliefs of the student or student's parent; or
8. income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

The IRB does not have the authority to issue a waiver of informed consent (i.e., parental permission) for research with minor students involving any of the areas of inquiry set forth in PPRA or to overrule school district policies for implementing PPRA. Researchers whose research is subject to the PPRA should review the policies of the local educational agency early in the study design process and should consider multiple methods to provide information to parents such as flyers or letters offering parents the opportunity to review the study materials. Investigators must also develop mechanisms for

obtained signed parental permission that do not single out students whose parents do or do not agree to allow their child to participate.

*\*Per the Department of Education, research or experimental program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.*

### **II4A-A3 Psychology and Social Psychology Subject Pools**

University students or students enrolled in other institutions within the Nevada System of Higher Education (NSHE) (e.g., TMCC ) may be offered the opportunity to participate in research for credit as part of a course requirement via the University Psychology and Social Psychology Subject Pools. For the latter, the requirements for obtaining site permission still apply. Investigators who wish to recruit students from external sites, including other NSHE institutions, must submit documentation of site permission from those sites. Additionally, the requirements for opportunities to earn credit for research participation and for non-research activities, summarized below, apply regardless of the students' institutional affiliations.

Students may not be *required* to participate in research for course credit and if credit is offered for research participation, a comparable non-research alternative must always be offered. To minimize the potential for coercion, alternatives to participating in research for course credit must be comparable in terms of time, effort, and fulfillment of course requirements(see IRB guidance II4A GD1 Extra Credit for Students Participating in Research).

As with all research participants, students must be free to withdraw from participation at any point in a study without penalty. Students who withdraw from a research study for course credit must receive credit for participation. When payment is offered, credit for payment accrues as the study progresses (as appropriate to the research) and is not contingent upon the student completing the entire study.

Study-specific informed consent is required as described by federal regulations and University policies. Parental permission and youth assent are required for University students (including high school students taking college courses) who meet the regulatory definition of children.