



Guidance: Research involving students and employees

Research involving potentially vulnerable populations must include additional protections to minimize the possibility of coercion or undue influence. Federal regulations provide specific protections for pregnant women and fetuses, prisoners, and children; however, considerations may also be necessary for other potentially vulnerable groups, such as students and employees.

The purpose of this guidance is to outline additional protections that investigators and IRBs should consider for research involving students and employees.

1. Definitions

Student refers to a person who is studying at a school or college, including undergraduates, graduate students, medical students, residents, fellows, doctoral students, etc.

Employee refers to a person employed for wages or salary, including full-time, part-time, temporary, visiting, student employee appointments, etc.

Conflict of interest involves a situation in which faculty, staff, or student employees have a financial interest or other personal consideration that may compromise, or have the appearance of compromising, their professional judgment in performing their University duties (e.g. teaching; clinical care; designing, conducting, or reporting research; business decision-making; or performing other University obligations).

Undue influence often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized. often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services or educational programs if he or she does not participate in the research.

Action research is defined as any systematic inquiry conducted by teachers, administrators, counselors, or others with a vested interest in the teaching and learning process or environment for the purpose of gathering information about how their schools operate, how they teach and how their students learn (Mills, 2011). Action research is characterized as research that is done by teachers for themselves as a systematic inquiry into one's own practice (Mertler, 201).



Considerations when participants are students

If you are a teacher or administrator working with students who are minors, and you intend to recruit students to whom you provide services, your IRB proposal should include clearly describe intent, address conflict of interest, and discuss how perception of coercion and undue influence risks will be minimized. This is a common research practice called *Action Research*.

Addressing Conflict of Interest

Your role at the school or institution should be clearly described. If you do plan on recruiting students that you serve, the protocol cannot state that there is no conflict of interest. When the subject pool is the researcher's own class, for example, participants are often recruited out of convenience and there may be more benefit to the researcher than to the participants. Past history and a continuing relationship with students can also bias a researcher and affect whether or not free informed consent and assent can truly be achieved. As Nolen & Vander Putten (2007) state "when the researcher is a member of and plays a role in a system under investigation, issues surrounding role definition, role ambiguity, and role conflict are often significantly greater than when a researcher enters the school as an objective outsider with the explicit purpose of conducting the study" (403).

Addressing undue influence

Undue influence can be subtle. For example, students might feel pressure to participate in research if everyone else in the class is doing so. Influence is contextual, and undue influence is likely to depend on an individual's situation, therefore, it can be difficult to strategize how undue influence can be minimized.

Despite the teacher-researcher's best intentions, the power imbalance between a teacher and student may contribute to a coercive atmosphere and affect the perception that participation is voluntary. As Hick's states in her article *Research in Public Schools* (2006), "It is difficult, if not impossible, to eliminate undue influence in a setting in which children's lives are orchestrated by adults and in which teachers are often important and, indeed, influential figures in children's lives"(341).

Parents and students may fear that non-agreement will affect their relationship with the teacher or how the students' performance is evaluated. Replicating official sounding verbiage in the protocol narrative that is provided on the consent form about the voluntariness of the research does not provide a sufficient resolution to decreasing an atmosphere of coercion. Researchers should demonstrate that they are invested in ensuring the voluntariness of the research by providing examples of strategies that will be employed to minimize coercion and promote meaningful and continued consent/assent. The protocol narrative needs to include a description of the tangible measures that will be used to minimize a coercive atmosphere.

Addressing coercion



Instructors have inherent power over students (e.g., through their responsibility for assigning grades). Because of this power relationship, it is likely that some students will feel pressure to comply with requests made by their instructors. This is true independent of whether the instructors actually try to pressure the students. For example, when instructors ask students to participate in research projects, some students may worry that not participating could influence the instructors' opinions of them or that their grade might be affected. Such potential concerns are problematic regardless of whether the instructor actually would think negatively of nonparticipation or whether the students' grades actually would be affected. Students' perceptions that such negative consequences could happen are enough to make them feel pressured to participate.

Thus, unless the research cannot be reasonably completed in another manner, instructors should not recruit participants from their own courses. However, there are cases in which the research cannot be feasibly completed without recruiting students from a particular course. For example, if the research project concerns a teaching method that will be implemented in the course, then the only possible subject pool comes from the students enrolled in that course. If a research project has a reasonable chance of yielding benefits, and the only feasible way to complete the study is to recruit in the researcher's course, the research may be permissible if the researcher is able to sufficiently reduce the potential for students to feel pressured to participate.

Strategies for minimizing coercion or perception of coercion

In the rare instances in which recruiting from one's own class is permissible; researchers are expected to minimize the potential for students to feel pressured to participate. The following are some examples of how coercion can be mitigated during recruitment.

- (i) Have a mechanism to withhold participant names from your knowledge until after the class has ended and the students are no longer under your instruction, or at least until after grades have been assigned.

For example, a research collaborator can run the study and keep any identifying information from the instructor. If a researcher designs a study in this way, two points are crucial:

BEFORE being asked to participate, potential subjects should be informed that the instructor will not know who did and who did not participate (at least until after final grades have been assigned).

The research should be designed so that the instructor cannot infer who participated through indirect means (e.g., by seeing who walks into a laboratory, by getting a list of who earned credit for participating in the study).

- (ii) Ask a neutral third party not involved in the research to recruit students on your behalf (it can be another teacher).



- (iii) Expand the subject population so that volunteers are sought not just from your own classroom but from other classrooms.
- (iv) Re-verify assent by developing data instruments to include a yes or no response item, stating “Please include my answers in the study,” which allows students to opt out of the study while still participating in classroom work.
- (v) Reduce peer pressure by including reasonable rewards for participation and attractive alternatives for those who don’t participate.,

When developing a protocol, several of the identified strategies may be used. Additional strategies may also be developed depending on the nature of your research, subject population, and the community in which research is conducted. Your strategies for minimizing coercion, alternatives to participating, and any rewards provided are to be detailed in both the protocol and informed consent process.

Considerations when participants are co-workers or subordinates of the researcher

When employees are targeted as potential research participants, there are the potential risks of coercion and undue influence being perceived. These risks can be exacerbated if the individual is being recruited by their employer, supervisor, or mentor. They may agree to participate in the study with hopes it will have a positive implication on their employment status or, they may fear that failure to participate may result in negative impact on their employment.

An individual’s decision to participate or not should not have affect, positive or negative, on future performance evaluations, career advancements, or other unfavorable employment-based decisions made by peers and/or supervisors. Therefore, recruitment efforts must be designed to minimize the possibility or any perception of coercion or undue influence. Furthermore, this population should not be selected as potential participants simply due to convenience. In general, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than from individuals who report directly to the investigator(s).

Strategies to Reduce Potential for Coercion or Undue Influence

Strategies to minimize the potential influence of an investigator when recruiting his/her own employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the investigator(s).

Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for investigators to keep an individual’s participation confidential, which could pose risks to participants, e.g., when stigma is associated with the condition or question under study or when peer pressure is a component of the research. In such situations, research should be conducted off-site and/or outside of regular work hours when possible to minimize potential risks.



In cases where regular workplace activities are also the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would take place even without the research.

Resources and References

Hicks, L. (2006). Research in Public Schools. In R.J. Amdur & E.A. Bankert (Eds.) Institutional Review Board Management and Function. (2nd ed., pp. 341-345). Sudbury, MA: Jones and Bartlett Publishers

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Mills, G. (2003). Action Research: A Guide for the Teacher Researcher (2nd ed.). Upper Saddle River, NJ: Merrill/Prentice Hall.

Nolen, A. L., & Vander Putten, J. (2007). Action Research in Education: Addressing Gaps in Ethical Principles and Practices. *Educational Researcher*, 36, 401-406.

[University of Pittsburgh](#)

[Saint Louis University](#)

[21 CFR 56.111](#)

[45 CFR 46.111](#)