

Vulnerable Populations -- Subordinates

Background

One of the regulatory requirements for IRB approval of research is equitable selection of subjects [45 CFR 46.111(a)(3)]. Specifically, regulations task the IRB with being “particularly cognizant” of participants who may be vulnerable to coercion or undue influence. Additionally, regulations require that the informed consent process must minimize the possibility of coercion or undue influence [45 CFR 46.116(a)(2)]. When studies involve people who may be vulnerable in these ways, researchers are responsible for adding safeguards to protect participant rights and welfare [45 CFR 46.111(b)]. This document discusses ethical issues that arise when persons in subordinate roles are included in research and provides examples of potential mitigating actions.

Subordinates as Research Participants

Coercion and Undue Influence

Students, employees, and other subordinates may experience a perceived or real sense of coercion to enroll in research conducted by an instructor, employer, or service provider. In addition, people could experience undue influence to take part in research related to their current course enrollment, employment, or program involvement.

Because vulnerable populations may anticipate negative effects based on their choice to participate or not, there is potential for people to feel pressured to take part in the study, particularly if data collection takes place during a scheduled course, work shift, or program. Foreseeable negative impacts could include fears about how managers or peers will treat them. For example, declining to enroll in a study conducted by or important to management could lead to a full spectrum of issues such as tense relationships, lower performance evaluation, job loss, etc., or the fear of such consequences. Students may be concerned about negative repercussions related to their position as a student (i.e., grades, future letters of recommendation, assistantships, etc.) if the investigator is an instructor, major professor/advisor, or active in their field of study. This vulnerability might also exist when recruiting students to enroll in studies related to their current or future course enrollment or academic program.

Pressure is heightened if supervisors/instructors invite subordinates to participate or are involved with data collection—it is very difficult to say “no” to one’s boss or instructor. Alternatively, a person may believe that choosing to participate will garner favor or benefit (e.g., better grades, favor with a supervisor, etc.).

Finally, there are some circumstances beyond the student and employment context that also could expose people to actual or perceived coercion or undue influence to enroll in a study. While such access involves different concerns than those related to employment or student status, researchers should pay attention to any imbalance of power. For example, parents who opt out of research conducted at their child’s preschool may worry about strained relationships with care providers, or food bank clients could have concerns about access to programs or support services if they withdraw from related research.

Privacy, Confidentiality, and Participant Risk

Implementing confidentiality and privacy protections takes on another layer of complexity when protecting subordinate participants. Research often involves gathering information from people that they would not normally share with their supervisors, instructors, faculty advisors, etc. For example, research participation may prompt subjects to disclose negative opinions or experiences related to their vulnerable context (e.g., assessments of their workplace culture or supervisor practices, opinions about instructor-effectiveness or teaching practices). Some studies request personal information, such as health information, substance use, sexual behaviors, or financial information; even seemingly benign information can feel risky to share with superiors (e.g., political opinions, religious practices, family background, purchasing habits, etc.).

Personal, professional, or even legal discomfort or risk is enhanced when participants can be linked to the information they provide in study data and/or study results. Anonymity is difficult to ensure when collecting information from persons known to the researcher. Basic demographic or background information is often enough for those familiar with the research setting to deduce identities. Moreover, some protocols prompt participants to provide examples or describe specific incidents. Even if participants don't specify names of individuals, organizations, or locations, people (participants or third parties) might be recognizable given enough related information.

Some physical interventions that are otherwise non-invasive raise extra privacy concerns if conducted with subordinates. For example, employees are likely to be very uncomfortable having a supervisor place biometric sensors on their skin under clothing, measure their weight, or collect blood or urine samples (and receive results of testing).

Because of their inherent vulnerability, subordinates can be included in research only when scientifically necessary, and researchers must adopt practices that minimize real or perceived undue influence or coercion and maximize privacy and confidentiality.

Actions to Consider

Mitigating Undue Influence or Coercion

When it is *scientifically necessary* to invite participants who are vulnerable to coercion or undue influence, consider the following mitigation strategies:

- Recruit participants broadly instead of relying only or primarily on employees or students of the researcher(s). For example, send recruitment messages to students or employees of a whole department/college/organization instead of focusing only on those in the researchers' classes, labs, or units.
- Use indirect recruitment methods that allow potential participants to initiate contact if they are interested. For example, post flyers instead of directly calling or emailing potential participants.

- When enrolling one's own students:
 - Establish procedures so that researcher-instructors don't know who has elected to take part in the research until after submitting grades for that semester.
 - Allow students an end-of-semester option to withdraw their consent, after they are familiar with the course material/information that will be used as study data.
- When including one's employees, have a research team member without a supervisory role handle recruitment and informed consent.
- Create a process in which instructors, employers, program leaders, etc. will not know who agreed to take part in the research. For example, a member of the research team not affiliated with the workplace/classroom could implement recruitment, obtain consent, and collect data.
- Ensure that the amount of compensation does not unduly influence decisions to enroll in the research. For protocols providing course/extra credit to student participants, the amount should not significantly increase an overall grade, and it is essential to provide non-research alternatives that are genuinely comparable to research participation in terms of time and effort.
- Explicitly convey the voluntary nature of participation in recruitment messages, consent processes, and throughout the study. Make sure people clearly understand that their decision of whether or not to take part in the research, or to withdraw at any time, will have no impact (positive or negative). Include related language in recruitment and consent materials, such as:
 - *Undergraduate students: "Your choice of whether or not to participate, or to leave the study early, will have no effect on you as a student, your grade in this course, or your relationship with the instructor, in any way."*
 - *Grad students/TAs/RAs: "Your choice of whether or not to participate, or to leave the study early, will have no effect on you as a student or employee, your academic performance, or your relationship with the research team, in any way."*
 - *Employees: "Your choice of whether or not to participate, or to leave the study early, will have no effect on you as an employee, or your relationship with your employer, in any way."*
 - *Organization members/Parents: "Your (your child's) choice of whether or not to participate, or to leave the study early, will have no effect on your (your child's) access to the organization, its programs or services."*

Minimizing Risk Due to Privacy or Confidentiality Concerns

When research involves sensitive, personal information collected from subordinates, additional privacy and confidentiality safeguards are necessary. Consider the following examples:

- Allow people as much privacy as possible related to their decision to enroll in the study. Provide participants plenty of time to consider and a private method to consent or decline. For example, for in-person procedures, distribute consent and data collection materials to ALL students enrolled in a course, and then collect materials from everyone at the same time, so as not to single out people who are/are not enrolling in the study. Minimize the information gathered to that which is scientifically necessary. Avoid detailed or specific background or demographic information when possible.
- Ensure privacy during data collection.
 - Conduct the research procedures out of sight by other employees/students whenever possible, particularly if the research involves procedures that may be embarrassing/uncomfortable to complete in front of colleagues/classmates.
 - Avoid group settings (e.g., focus groups) for research that gathers information persons may not want their colleagues or classmates to know. Ask participants to protect group and individual privacy and confidentiality by not discussing who was present or what was shared.
- Have interactions with participants (consent, data collection, etc.) handled by a research team member who is not affiliated with the workplace or course; ensure the supervisor(s) work with fully-de-identified responses (this may not be feasible in many cases). Advise participants to use personal (not work-issued) contact methods for study communication, such as personal devices, accounts, and phone numbers.
- Carefully assess information included in presentations and publications related to the study to ensure participants' identities cannot be deduced by those familiar with the research setting. Redact or recode information that directly or indirectly identifies people, locations, or organizations.
 - Consider whether it is necessary to share information that may disrupt workplace relationships (if a colleague or superior were to read it).
- Employ a "member checking" process and allow participants the opportunity to review data collected from/about them and/or descriptions of them in publications/presentations, so they can point out potentially identifying information and/or information that may present risk.
- Inform participants -- acknowledge the unique privacy/confidentiality concerns and explain how you are addressing them.
 - Explicitly inform participants that they can decline to provide information or complete procedures that make them uncomfortable.
 - Clearly inform participants of limits to privacy and confidentiality, along with any associated risks or discomforts.

- Inform participants about any plans to present findings to or share reports with their schools/class or workplaces, and what that might mean for them (e.g., a colleague or peer might figure out that they were involved in the study or the information they shared).

Other Considerations

Use of Employment or Student Data

Researchers often have multiple roles that afford access to information about students or employees (education records, employment records, etc.). Regardless of this access, these records/data generally cannot be used for research without permission of the student/employee or permission from appropriate entities at Iowa State (e.g., the ISU Registrar, University Human Resources, etc.).

Use of Class or Work Time

Care must be taken that the research does not adversely affect participants or others. Research activities completed during work time may make completing normal work activities difficult. Research during scheduled class time may reduce time available for normal educational activities. Additionally, effects on non-participating third parties should be considered. For example, a non-participant may have to alter their work activities to “cover” for a participant whose time is diverted to the research.

Role Confusion

Role confusion may occur when research activities are embedded in normal educational or workplace activities. Researchers must clearly distinguish between voluntary research activities and those required for work or class purposes that would take place regardless of the research. When research procedures are not overt/obvious, such as observation of class or work activities, participants may not realize that their comments or behaviors are being tracked for the research. Researchers should take extra care to ensure that participants are well informed; offering the ability to go “off the record” may also be appropriate.

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