



## Guidance: Research involving 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 employees.

### 1. Definitions

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.

### 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 of 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**

[21 CFR 56.111](#)

[45 CFR 46.111](#)