



RECRUITMENT AND ENROLLMENT OF EMPLOYEES IN RESEARCH

Background

Under certain circumstances, employees may not feel free to refuse if asked to participate in research. Employees may feel pressure to participate in research, particularly if the workplace is one that encourages research participation. The perception of expectations to participate in research may be coercive. In rare occasions, pressure may be more pronounced, in that employees may fear that the lack of participation could result in negative consequences with respect to their employment.

Employees may be exposed to a greater at risk of invasion of privacy than are other research participants who have no association with the sponsoring institution. For example, co-workers and workplace friends of employees participating in research may have access to research data and may obtain and share personal information about research subjects.

Definitions

Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Code of Federal Regulations Title 45 Part 46 Subpart A Section 46.102*

Human subject - living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. *Code of Federal Regulations Title 45 Part 46 Subpart A Section 46.102*

Minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. *Code of Federal Regulations Title 45 Part 46 Subpart A Section 46.102*

Employee - an individual who is contracted to receive a salary or other compensation from the University of University, Primary Children's Hospital, Veteran Affairs Salt Lake City Health Care Services, Shriners' Hospital for Children, or any subsidiary thereof (hereafter referred to as *employees*) in return for services performed on a full-time, part-time, limited-time, temporary, contracted, or casual basis.

Direct supervision - having the authority to evaluate performance, recommend pay raises and/or promotions, or hire and fire employees.

Description

Recruitment

Investigators and research staff may not directly invite employees to participate in research on a personal basis.

Acceptable recruitment methods include the posting of flyers approved by an IRB and the placement of advertisements approved by an IRB. E-mails or letters may be sent to employees if they have previously agreed to receive invitations to participate in research.

Minimal Risk Research

Enrollment in research activities that have been designated "minimal risk" by an IRB is open to all employees. This includes research determined to be exempt by the University of Utah IRB.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Greater-than-Minimal Risk Research

Employees may not enroll in research that is designated “greater-than-minimal risk” by an IRB if 1) they are directly supervised by an investigator (principal or co-investigator) of the research; 2) their direct supervisor reports to an investigator (principal or co-investigator) of the research.

Restrictions on the enrollment of employees in greater-than-minimal risk research is not intended to bar an employee from participating as a research subject where it is in the medical best interests of the employee to do so. Investigators should notify and seek the approval of the IRB in such circumstances. The IRB chairs or their designee may approve the enrollment of an employee in such circumstances on a case-by-case basis.

An IRB has the authority to determine that employees may be enrolled in greater-than-minimal risk research in exceptional situations. The convened IRB must determine and document that the research is of significant importance and cannot be conducted without the enrollment of these employees.

Privacy and Confidentiality

The risk of a breach of confidentiality is greater when research participants are employees, particularly when those employees are known by the research staff. Whenever employees participate in research, regardless of level of risk or prospect of direct medical benefit, investigators must provide the IRB with specific plans for ensuring that the privacy and confidentiality of these employees will be respected. These plans must take into account and adequately address the special concerns raised by the workplace context.

Points to Address

New Study Application

- 1. Participants page, question number 3:** Select “Students, staff, or faculty of the research institution”.
- 2. Vulnerable Populations page:** Complete the vulnerable populations page by providing justification for the inclusion of employees as research participants.
- 3. Data Monitoring Plan page:** Provide specific details of the plan to protect privacy and confidentiality considering the special circumstances of employees enrolled in research.

References & Links

IRB SOP 501: Vulnerable Populations

<http://irb.utah.edu/guidelines/irb-sops.php>

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