



RECRUITMENT AND ENROLLMENT OF EMPLOYEES IN RESEARCH

Adopted from policy written by Johns Hopkins Medicine Institutional Review Board

Description Background

Relatively little attention has been paid to the question of whether, or under what conditions, employees of an institution should be permitted to serve as subjects in human research conducted by that institution. Federal regulations governing research with human subjects provide no specific guidance. There is also little guidance in the scholarly literature on this aspect of research ethics. A review of the literature from 1966 to 2002 conducted through PubMed and citation searches found no articles dealing specifically with the topic of university employees participating in research conducted at academic institutions. Two articles addressed the issue of pharmaceutical employees participating in research conducted by their employers (Butler 1978; Meyers 1979). The Committee conducted an informal survey of twenty academic medical centers and universities, eighteen of which responded. Seven had policies governing the involvement of employees in research; eleven did not.

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The Office of Human Research Protections (OHRP) discusses employees under the heading of "Special Classes of Subjects" in its IRB Guidebook. The OHRP advises attention to matters of voluntariness, undue inducement, and confidentiality and recommends avoiding individual solicitations to participate in research. The central ethical concern with respect to the recruitment of employees in research is that, under certain circumstances, employees may not feel free to refuse if asked to participate in research. Although outright coercion is unlikely in the workplace, employees may feel pressure to participate in research, particularly if the workplace is one that encourages. This pressure may be subtle, as when a culture of expectations emerges in a work unit that reinforces and encourages employees to participate in research participation. The perception of expectations to participate in research may, 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. Alternatively, the pressure may be more overt, with individuals fearing that their interests as employees may be adversely affected if they do not participate.

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The Centers for Disease Control and Prevention (CDC) likewise provides guidance regarding employee participation in research. Research involving CDC employees as subjects must conform to special requirements. For example, investigators must supply the IRB with a list of employee subjects and potential employee subjects must be notified that they can file complaints with relevant CDC administrators about perceived coercion.

The central ethical concern with respect to employees is that, under certain circumstances, they may not feel free to refuse. Although outright coercion is unlikely in the workplace, employees may feel pressure to participate. This pressure may be subtle, as when a culture of expectations emerges in a work unit that reinforces and encourages employees to participate in research. Alternatively, the pressure may be more overt, with individuals fearing that their interests as employees may be adversely affected if they do not participate.

Another ethical concern is that employees may be exposed to a greater, more 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, for whatever reasons, may obtain and share personal information about research subjects.

Voluntariness of consent and invasion of privacy are not the only ethical considerations raised by policies governing employees participating as research subjects. Universities and academic medical centers are work environments that disproportionately attract as employees people who are supportive of, and often committed to, the advancement of human welfare through research. Employees who are so motivated may have a sincere preference to participate in research. In at least some cases, prohibiting employees from participating as research subjects would restrict individuals from pursuing

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~~their autonomous preferences.~~

~~A blanket prohibition on the enrollment of employees in research also could have implications for fairness in the distribution of the burdens of research and how this distribution is viewed by the wider community. Although such a prohibition would be justified primarily by concerns about the voluntary nature of consents obtained from employees, it would have the effect of protecting employees from any research-related risks and burdens. These risks and burdens would then have to be borne by individuals outside the institution who could reasonably ask why they should volunteer when the institution protects its own employees from the risks of research participation.~~

~~The challenge before the Committee was to identify a policy that adequately addressed these considerations. We also strove to craft a policy that could provide practical guidance for those who would be charged with implementation, including institutional review boards.~~

Definitions

~~A. **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*~~

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~~B. **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*~~

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~~C. **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*~~

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~~D. **Employee** - an individual who is contracted to receive a salary or other compensation from the University of Utah, 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.~~

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

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Policy Description

~~A. **Immediate Family Members**~~

~~The following recommendations apply both to immediate family members of employees, as well as to employees themselves.~~

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Recruitment

~~Employees may not be directly solicited to enroll in research, regardless of the level of risk. Investigators and research staff may not directly invite employees to participate in research on a personal basis.~~

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~~B. 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.~~

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C. 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.](#)

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D. Greater/More-than-Minimal Risk Research

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

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1. Examples

~~Division X consists of a Division Head, Dr. A, faculty members, Drs. B, C, and D, and several fellows. Drs. A, B, C, D all have administrative and research staff. No employee of the Division may enroll in more than minimal risk research in which Dr. A is a primary or co-investigator. Dr. A and his/her staff members may enroll in more than minimal risk research in which Dr. B, C, or D is a primary or co-investigator.~~

~~Dr. B may enroll in more than minimal risk research in which Dr. C or Dr. D is a primary or co-investigator. Similarly, Dr. B's staff may enroll in more than minimal risk research in which Dr. C or D is a primary or co-investigator. However, if Dr. B is a co-investigator on Dr. C's research, then Dr. B's staff may not participate as subjects in Dr. C's research if that research is more than minimal risk.~~

~~Fellows of Division X may not enroll in more than minimal risk research in which Drs. A, B, C, or D are primary or co-investigators.~~

2. Exceptions

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a) Research that offers a Reasonable Prospect of Direct Medical Benefit to Research Participants

Restrictions on the enrollment of employees in ~~greater~~more-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 need to~~ notify and seek the approval of the IRB in such ~~exceptional~~ circumstances. ~~The IRB chairs or their designee may approve the enrollment of an employee in such circumstances on a case-by-case basis.~~

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b)

c) IRB Waiver

An IRB has the ~~may authority to determine that waive~~ restrictions on the enrollment of employees ~~may be enrolled in~~ ~~more~~greater-than-minimal risk research ~~in exceptional situations. UNDER EXCEPTIONAL SITUATIONS ONLY where t~~ ~~The convened IRB must determine and document~~ that the research is of significant importance and cannot be conducted without the enrollment of these employees.

E. Privacy and Confidentiality

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~~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

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



New Study Application

1. Participants page, Under Participants, question number 3 - Select "Students, staff, or faculty of the research institution".

2. Complete the "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.

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References & Links

IRB SOP 501: Vulnerable Populations

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

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