

Policy Governing the Recruitment and Enrollment of Employees in Research Involving Human Subjects

Submitted by the Committee on Participation Policies for Human Subjects Research
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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.

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 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 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 who have access to research data may, for whatever reasons, 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 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.

Policy Recommendations

I. 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

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

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

D. Employee - an individual who is contracted to receive a salary or other compensation from Johns Hopkins University, Johns Hopkins Hospital, Johns Hopkins Health System, or any subsidiary thereof in return for services performed on a full-time, part-time, limited-time, temporary, contracted, or casual basis

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

II. Policy

A. Immediate Family Members

The follows recommendations apply both to immediate family members of Johns Hopkins employees, as well as to employees themselves.

B. Recruitment

Employees may not be directly solicited to enroll in research, regardless of the level of risk. Acceptable recruitment methods include the posting of flyers approved by an IRB and the placement of advertisements approved by an IRB.

C. Minimal Risk Research

Enrollment in research activities that have been designated “minimal risk” by an IRB is open to all Hopkins employees.

D. More-than-Minimal Risk Research

Hopkins employees may not enroll in research that is designated “more-than-minimal risk” by an IRB IF they are directly supervised by an investigator (principal or co-investigator) of the research. Hopkins employees may also not enroll in research that is designated more-than-minimal risk IF their direct supervisor reports to an investigator (principal or co-investigator) of the research.

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

2a. Research that offers a Reasonable Prospect of Direct Medical Benefit to Research Participants

Restrictions on the enrollment of employees in 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 need to notify and seek the approval of the IRB in such exceptional circumstances.

2b. IRB Waiver

An IRB has the authority to waive restrictions on the enrollment of employees in more-than-minimal risk research **UNDER EXCEPTIONAL SITUATIONS ONLY** where the IRB determines that the research is of significant importance and cannot be conducted without the enrollment of these employees.

E. Confidentiality

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 of these employees will be respected. These plans must take into account and adequately address the special concerns raised by the workplace context.