



Enrolling Employees in Human Subject Research Policy

Guideline: GEN010
 Responsible Executive: Provost & Vice President for Academic Affairs
 Responsible Office: Office of the Provost
 Approved by: Senior Planning Group
 Effective: 01/21/2020
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Policy Statement

This policy is intended to address ethical concerns when employees of the Johns Hopkins University (“JHU”) are recruited to participate as research subjects at JHU. Under certain circumstances employees’ ability to make voluntary choices and privacy could be compromised, this policy intends to protect employees while recognizing the rights and the interests of employees to participate in research.

Who Is Governed By These Guidelines

All units of JHU, including the Applied Physics Laboratory.

Purpose

The Committee on Participation Policies for Human Subjects Research (“The Committee”), convened in 2003, considered ethical concerns about JHU employees participating as research subjects in research conducted at the institution in which they are employed. The Committee concluded that, under certain circumstances, employees may not feel free to refuse to participate, and/or the increased risk of invasion of privacy due to personal relationships with those who have access to research data. JHU weighed its concern for employees against its obligation to respect the choices of employees who

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genuinely and voluntarily wish to participate in research that has been vetted by an Institutional Review Board (“IRB”) as ethically acceptable. This policy reflects the striking of that balance for research conducted at JHU.

Definitions

Research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. See 45 C.F.R. § 46.102(l) and Maryland Ann. Code, Health-General Article § 13-2002.
Human Subject	A living individual about whom an investigator (whether professional or employee) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Employee	An individual who receives a salary, a stipend, or other compensation from JHU, or the Johns Hopkins Hospital, the Johns Hopkins Health System, and any affiliate or subsidiary there of (collectively “JHHS”) in return for services performed on a full-time, part-time, limited-time, temporary, contracted, or casual basis.
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.
Direct Supervision	Having the authority to evaluate performance, recommend pay raises and/or promotions, or hire and fire an employee.
Institutional Review Board (“IRB”)	A board appointed by an Institutional Officer under the JHU Policy for Institutional Review Board Authority, with a composition that meets the requirements of 45 CFR Part 46, and for clinical investigations, 21 CFR Part 56. IRB includes both IRBs appointed under the JHU Policy and IRBs that are serving as the IRB of record under an executed IRB Reliance Agreement.

Policy

All proposed research (as defined above) subject to JHU Policy GEN002 that involves the proposed recruitment of employees (as defined above) shall be reviewed by the responsible IRB for compliance with this Policy.

A. Recruitment of Employees

1. JHU employees may not be recruited to enroll in JHU research by their direct supervisor, regardless of the level of risk.
2. Acceptable recruitment methods include the posting of flyers or sending of messages approved by the IRB and the placement of advertisements approved by the IRB. Research studies that directly target or are limited in enrollment to JHU employees shall be referred to the responsible, JHU central human resources office and the JHU Chief Risk Officer to ensure that the research will not interfere with work duties or impact employment. Where the research study directly targets or is limited in enrollment to JHH employees, the IRB may refer the study to the responsible human resources office at the relevant JHH entity. Investigators must provide explicit justification for the targeting of JHU employees to ensure equitable subject selection.

B. Participation Compensation

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1. The use of monetary compensation for JHU employee participation in research is permissible but must be guided by the same considerations and constraints as those applicable to all human subjects.
- C. Restrictions on Obtaining Informed Consent**
1. JHU employees may enroll in research involving activities that have been designated “minimal risk” and “greater than minimal risk” by a JHU IRB, provided they are not consented by a direct supervisor.
- D. Exempt and Non-Exempt Research**
1. The provisions of this Policy apply to both exempt and non-exempt research, as defined in applicable regulations.

Procedures

A. Institutional Review Board Approval

1. IRB application materials shall document whether JHU employees will be targeted as participants in the research.

B. Workplace Practice Research

1. Research involving the effectiveness of workplace training, practices, or changes in the working environment for JHU employees shall be referred by any IRB to the responsible central JHU human resources office and JHU Chief Risk Officer (for JHU employees only) and to the responsible JHHS human resources department in the JHHS entity (for JHHS employees only) where the research is to be held to confirm that the proposal will not interfere with the working environment for their employees. In such cases, the responsible School or subunit will be notified by the IRB when a protocol that has been referred for review is approved.

Policy Enforcement

Reporting Violations	All members of the JHU community have an obligation to report good faith concerns regarding violations of IRB protocols or policies within the scope of this Policy. Violations may be reported to the appropriate IRB Office, or through the Compliance Hotline
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Related Resources

University Policies and Documents	
<ul style="list-style-type: none"> • JHU Homewood IRB Policies: http://homewoodirb.jhu.edu/ • JHM IRB Policies: https://www.hopkinsmedicine.org/institutional_review_board/index.html • JHSPH IRB Policies: https://www.jhsph.edu/offices-and-services/institutional-review-board/index.html 	
External Documentation	
<ul style="list-style-type: none"> • The Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html • 45 CFR Part 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html • 21 CFR Part 50: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50 • The Maryland Annotated Code, Health-General Article 13-2003 (The Hubbard Act): http://mgaleg.maryland.gov/2020RS/Statute_Web/ghg/13-2003.pdf 	

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Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Institutional Review Board Offices		
Anonymous Reporting/Ethics Line	Johns Hopkins University and Health System Compliance Line	1-844-SPEAK2US	https://johnshopkinsspeak2us.tnwreports.com/
Reporting violations of civil or criminal law	Office of the Vice President and General Counsel	410-516-8128	http://web.jhu.edu/administration/general_counsel/
Reporting allegations of research misconduct	Research Integrity Officer	410-516-6880	https://provost.jhu.edu/members/jonathan-links/

Web Addresses for Guidelines<https://policies.jhu.edu/>