



Enrolling Students in Human Subject Research Policy

Policy: GEN011
Responsible Executive: Provost &
Vice President for Academic Affairs
Responsible Office: Office of the
Provost
Approved by: Senior Planning Group
Effective: 01/21/2020
Last Revised: N/A

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Policy Statement

This policy is intended to protect students who are asked to participate as research subjects at the Johns Hopkins University (“JHU”) under circumstances that could compromise students’ ability to make voluntary choices, while recognizing the rights and the interests of students to participate in research under circumstances where these concerns do not apply.

Who Is Governed By This Policy

All units of JHU, including the Applied Physics Laboratory.

Purpose

Ethical concerns about students participating as research subjects in research conducted at the institution in which they are enrolled were studied by a committee convened by the President of JHU in 2005. The Committee concluded that, under certain circumstances, students may not feel free to refuse to participate, and/or the granting of extra credit or academic credit for participation in research projects may create inappropriate pressures. JHU weighed its concern for students against its obligation to respect the choices of students who genuinely and voluntarily wish to participate in research that has been vetted

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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 student) 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.
Student	An individual who has registered within any academic division of the Johns Hopkins University, regardless of whether he/she is enrolled in courses or on authorized leave. However, a person who is employed full-time by JHU and is also registered for at least one course shall only be considered a student under this policy for the division of JHU in which the person is enrolled.
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.
Academic Supervision	The process by which an instructor evaluates the performance of a student through grades, extra credit, recommendations, supervision of student research, or other standardized feedback.
Education Research	Scholarly inquiry with the ultimate goal of improving the educational process or learning environment.
Institutional Review Board (“IRB”)	A board appointed by an Institutional Official 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 students shall be reviewed by the responsible IRB for compliance with this Policy.

A. Recruitment of Students

1. Research conducted by JHU investigators may only target students where the purpose of the research is related to their status as students. The investigator must provide explicit justification for the targeting of JHU students to ensure equitable subject selection.
2. A JHU investigator, including student investigators, may not directly recruit participation in his/her research project from any JHU student whom the investigator teaches or academically supervises, regardless of the level of risk of the study. This prohibition applies even if the student has previously indicated willingness to be contacted about the possibility of participating in research; for instance, by allowing his/her name to be posted within a research pool. Students who submit their names to a research

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pool may be directly contacted by phone or email if neither the recruiter nor the investigator supervise the student academically.

3. JHU students may be recruited through indirect methods such as the posting of IRB-approved flyers and/or the placement of IRB-approved advertisements including electronic advertisements.

B. Recruitment of Students Under the Age of Eighteen

1. Research involving JHU students under the age of eighteen is subject to the same regulations and guidance as all research involving minors. Investigators have the responsibility of ensuring that any potential student participants who are minors are identified and their enrollment complies with these regulations. The responsible IRB (listed below) can provide additional guidance.

C. Participation Compensation

1. The use of monetary compensation for JHU student participation in research is permissible but must be guided by the same considerations and constraints as those applicable to all human subjects.
2. The use of extra credit as a form of compensation for JHU student participation in research is acceptable if such participation offers educational benefits to the students in question, and the students are offered non-research alternatives by which they may earn an equivalent amount of extra credit. Appropriate non-research alternatives may include such activities as attending a departmental seminar or event, watching an educational film, or writing an essay. Alternatives must not entail more time, effort, or stress on the part of the student than participation in the research activity (e.g., writing a five-page essay is not proportional to the task of filling out a two-page survey). Other restrictions on the use of extra credit as an incentive to participation are at the discretion of the IRB and the academic department.

D. Restrictions on Obtaining Informed Consent

1. JHU students 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 to by an investigator-instructor who teaches or academically supervises that student.

E. 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 submitted by the principal investigator shall expressly state whether JHU students will be targeted as participants in the research.

B. Educational Research

1. Research involving educational effectiveness, pedagogical techniques, or changes in the learning environment for JHU students or trainees shall be referred by any IRB to the responsible offices in the School or division where research is to be held and/or to the Chief Risk Officer of JHU to confirm that the proposal will not interfere with the learning environment for their students or trainees. In such cases, the responsible School or division will be notified by the IRB when a protocol that has been referred for review has been approved.

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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

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 This Policy<https://policies.jhu.edu/>