

Policy Concerning the Recruitment and Enrollment of Students in Research Involving Human Subjects

Approved December 16, 2005

There has been increasing concern in recent years in the academic community about protecting the rights and welfare of potential human subjects, particularly those who may not be well positioned to protect their own interests. Although there are a variety of groups and individuals who fit this definition, such as prisoners and children, there has also been concern expressed for employees participating in research at the academic institution where they are employed. There have been similar concerns expressed about students participating in research conducted at the institution in which they are enrolled. President Brody appointed a committee chaired by Ruth Faden to review these issues and make recommendations concerning the recruitment and enrollment of employees and students in research conducted under the auspices of the Johns Hopkins University. The Committee has reviewed and evaluated the ethical issues related to voluntariness, undue inducement, and confidentiality as they relate to students and employees. A separate policy governing employees is being issued at this same time.

The primary concern with respect to students is the possibility that, under certain circumstances, they may not feel free to refuse to participate. For example, the ability of students to refuse may be compromised if the research is conducted by faculty members from whom they are taking courses or with whom they have some academic relationship as an advisee or mentee. The worry is that students may feel subtle but real pressure to

participate in research that is under the direction of people who have some control over their academic success and academic future.

An additional issue is posed by the granting of extra credit or academic credit for participation in research projects. Also of concern is the possibility that students may be more at risk for an invasion of privacy than other research participants who have no association with the University. For example, fellow students and friends of students may have access to research data and thus to personal information about student subjects. However, the University needs to be mindful that students are presumed to be competent adults.

The University must weigh 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 by an institutional review board as ethically acceptable. In addition, the University must take into account that the risk and burdens of research participation should not necessarily be incurred only by those individuals outside the institution. The policy described below attempts to strike a balance between these competing concerns. It is intended to protect students under circumstances that could compromise students' abilities to make voluntary choices, while recognizing the rights and the interests of students to participate in research under different circumstances where these concerns do not apply.

**THE JOHNS HOPKINS UNIVERSITY POLICY
GOVERNING THE RECRUITMENT AND ENROLLMENT
OF JOHNS HOPKINS UNIVERSITY STUDENTS
IN RESEARCH INVOLVING HUMAN SUBJECTS**

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** – a 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. Student** – an individual who has registered within any academic division of Johns Hopkins University, regardless of whether s/he is enrolled in courses or on authorized leave. However, a person who is employed full-time by the University and is also registered for a course (s) shall only be considered a student under this policy for the division of the University in which the person is enrolled.

- D. 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

- E. Medical Best Interest** – a situation in which participation in clinical research affords a student with a medical condition the best chances of achieving a desired medical outcome.

- F. 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.

- G. Education Research-** scholarly inquiry with the ultimate goal of improving the educational process or learning environment

II. Policy

A. Institutional Review Board Approval

Institutional Review Board (IRB) application forms should include an item inquiring whether it is anticipated that Johns Hopkins University (JHU) students will be enrolled as participants in the research. IRBs are encouraged, but not required, to have JHU students serve as IRB members, either in standing capacity or as ad-hoc members when protocols involving student research participation are anticipated.

B. Recruitment

An investigator, whether faculty member or student, may not directly solicit participation in her research project from any JHU student whom the investigator teaches or academically supervises, regardless of the level of risk. 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 her name to be posted within a research pool.

JHU students may be recruited through indirect methods such as the posting of IRB-approved flyers and/or the placement of IRB-approved advertisements. Students who submit their names to a research pool may be directly contacted by phone or email if neither the recruiter nor the investigator supervise the student academically.

C. Recruitment of Students Under the Age of Eighteen

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.

D. Participation Incentives

The use of monetary incentives for soliciting JHU student participation in research is permissible but must be guided by the same considerations and constraints as those applicable to all human subjects.

The use of extra credit as an incentive for JHU student research participation 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 the research activity (e.g., writing a five page essay is not proportional to the task of filling out a 2 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.

E. Minimal Risk Research

Enrollment in research activities that have been designated “minimal risk” by a JHU IRB is open to all JHU students. While investigator- instructors may not directly recruit their own students, they may enroll their students as research participants should the students respond to non-directed recruitment methods.

1. Exceptions: Educational Research

For *minimal risk* educational research, IRBs may waive the requirement for informed consent or the prohibition against faculty recruitment of their own students, based on the burden, risk and extent of departure from standard educational practice that the proposed research involves and the need for the exception

F. More-than-Minimal Risk Research

For research that a JHU IRB has designated “more-than-minimal risk”, an investigator may not enroll as a research participant: 1) any JHU student whom the investigator supervises academically or 2) any undergraduate student.

1. Exceptions

1a. Research that offers a Reasonable Prospect of Direct Medical Benefit to Research Participants

Restrictions on the enrollment of JHU students in more-than-minimal risk research is not intended to bar a student from participating as a research subject where it is in the medical best interests of the student to do so. Investigators need to notify and seek the approval of the IRB in such exceptional circumstances.

1b. Educational Research

For educational research that is *more-than-minimal risk*, the IRB may grant an exception to the prohibition against the recruitment of students by academic supervisors if the research question is directed to a concern or problem that is specific to students as a group and the

concern under investigation can only be addressed by research involving students. For example, if the concern is stress and mental health problems amongst medical students, an IRB may grant an exception to the prohibition on enrolling students for a research project that is otherwise ethically acceptable aimed at evaluating an educational intervention intended to decrease stress in medical students even if the research will collect sensitive information about mental health and drug use that might pose more than minimal risk to student participants.

G. Educational Research

1. Divisions of the University in which faculty are engaged in educational research should create a committee to monitor educational research involving their students. This committee should be appointed through the office of the Dean for Education/Dean of Students, in conjunction with educational policy committees of the faculty where applicable. The purpose of this committee is to ensure that students as a group, or in cohorts by class or other grouping, are not “over studied” or otherwise excessively burdened.
2. All educational research involving students should be submitted for review to an IRB, without exception.
3. The IRB will consult with the educational research committee but the final determination of the acceptability of any educational research project will rest with the IRB.
4. For *minimal risk* educational research, IRBs may waive the requirement for informed consent or the prohibition against faculty recruitment of their own students, based on the burden, risk and extent of departure from standard educational practice that the proposed research involves and the need for the exception.
5. Divisions with faculty engaged in educational research will have a public policy, widely posted including in their student handbook, indicating that all educational research involving students will be reviewed by both an Educational Research Committee and by an IRB. In some cases, educational research may be conducted without the express consent of students but only after review by the Educational Research Committee and only after an IRB has determined that the research is of minimal risk to students, is not burdensome and does not depart significantly from standard educational practices.
6. For educational research that is *more-than-minimal risk*, the IRB may grant an exception to the prohibition against the recruitment of students by academic supervisors if the research question is directed to a concern or problem that is specific to students as a group and the concern under investigation can only be addressed by research involving students. For example, if the concern is stress and mental health problems amongst medical students, an IRB may grant an exception to the prohibition on enrolling students for a research project

that is otherwise ethically acceptable aimed at evaluating an educational intervention intended to decrease stress in medical students even if the research will collect sensitive information about mental health and drug use that might pose more than minimal risk to student participants.

H. Confidentiality

Whenever JHU students 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 students will be respected.

These plans must take into account and adequately address the special concerns raised by the educational context.

I. Notification to Deans

IRBs will notify the relevant Dean(s) when a protocol anticipating the enrollment of Hopkins students is approved.

J. Exempt Research

Activities designated by a JHU IRB as exempt from IRB review are likewise exempt from these policies governing the recruitment and enrollment of JHU students.