
Yale University Institutional Review Boards

IRB Policy 350 Participation of Yale Students and Employees in Research

Responsible Office	Provost	Effective Date	April 1, 2009
Responsible Official	Human Research Protection Administrator	Revised	March 17, 2009

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Scope

This policy defines the standards and parameters for Yale students, fellows and trainees to be recruited as participants in instructor-initiated research (includes faculty and graduate student instructors) and employees recruited for employer-initiated/sponsored research. The policy is applicable both to research conducted by Yale faculty or staff as well as to non-Yale research specifically targeting Yale students, trainees or Yale employees for recruitment. It does not apply to projects that incidentally recruit Yale students, trainees or employees.

Policy Statement

All Yale students, fellows, trainees and employees enrolled as participants in research will be treated in a manner commensurate with their special status. Such individuals are vulnerable to coercion and, in the case of undergraduate students, may be minors. Additional safeguards must be implemented to protect their rights and welfare (45 CFR 46.111(b) and 21 CFR 56.111(b)), as described below.

Reason for the Policy

The Yale employment or educational setting may be coercive to potential participants if they perceive that continued employment, academic standing, or other benefits are dependent upon their participation in research. Researchers must acknowledge that recruiting their own students or staff to participate in research may place these individuals in a compromised position, and should be mindful of their ability to influence others when directly recruiting their own students and/or employees as research participants. Investigators should pay particular attention to the circumstances surrounding the research and whether the students/employees may feel pressure to participate in research because of his/her relationship with the investigator. Recruitment methods and activities must be conducted to assure the potential participant that his/her job, promotion, or course grade, for example, are not dependent upon his/her participation.

Definitions

Employee

For purposes of this policy, employee refers to a person employed by Yale University.

Fellow

A title given to postdoctoral scholars who are extending closely supervised training, established scholars and other distinguished individuals (e.g., faculty on leave from other institutions, government

officials, journalists, and writers) whose associations with the University and residence in the community for a limited period will be of mutual benefit. No teaching or work for the University is required. Visiting fellows are neither members of the faculty, nor Yale employees, and they receive no compensation from the University.

Student

For purposes of this policy, student refers to a person with whom the Yale investigator has an academic instructional or mentoring relationship.

Trainee

For purposes of this policy, trainee refers to a person who is in the process of being formally trained by a research mentor, typically senior Yale faculty.

Policy Sections

0000.1 Prohibition on Required Enrollment

A student shall not be required to enroll in University research as a research participant as part of a course requirement. Similarly, an employee shall not be required to enroll in employer-initiated research as a condition of employment.

0000.2 Students as Research Subjects

Investigators enrolling their own or their institution's students or trainees in research must:

- Not directly interact with and trainees who report directly to the investigator for recruitment purposes unless one of the special situations apply (see Special Situations below).
- Ensure that students understand that they may choose not to participate in the research and that their decision will not affect their grade/class standing.
- Avoid using class time to recruit or engage in the research.
- Limit the use of extra credit as compensation; it should not significantly increase a student's overall grade, and should be one of several comparable options for extra credit.
- Provide students with an equal alternative to participation, which should be comparable in terms of effort, time commitment, and credit given.
- Outline procedures in the research protocol to ensure that the students will not be subject to undue influence or coercion and to ensure that the student's privacy will be respected.
- Ensure that the requirements of IRB Policy 310 are met if the student population may include minors.

0000.3 Employees as Research Subjects

Investigators enrolling their own or their institution's employees in research must:

- Not directly interact with employees that report directly to the investigator for recruitment purposes unless one of the special situations apply (see Special Situations below).
- Engage in recruitment and consent activities outside of the presence of the employee's supervisor(s) whenever possible.

- Ensure that employees understand that they may choose not to participate in the research and that their decision will not affect their employment or performance evaluation.
- Outline procedures to ensure that the employees will not be subject to undue influence or coercion and to ensure that each employee's privacy will be respected.
- Ensure that steps are taken to avoid informing supervisors whenever possible of employees who decline participation.
- Conduct the research procedures out of sight of other employees whenever possible. For example, surveys or questionnaires could be given to employee participants to complete at home and mail back to the investigators instead of asking all employee participants to convene in a room on-site, which could identify them as research participants to their superiors and co-workers.

Investigators recruiting their research sponsor's employees in research must, in addition to the aforementioned requirements, ensure that all data given to the employer is either in the aggregate or is stripped of all identifiers so that the employee participant's identity is protected.

0000.4 Students or Employees as Subjects of non-Yale-Conducted Research

External investigators conducting research projects that do not involve Yale faculty but involve recruitment targeted specifically at members of the Yale community as a defined group must obtain approval from the appropriate official responsible for the group to be recruited. Review by a Yale IRB is not required when the University is not engaged in the research as defined in IRB Policy 100.

Special Situations/Exceptions

Permitted Convenience Sampling

While convenience sampling of an investigator's own students or staff is generally prohibited of the investigator, such individuals may elect to participate in research if they approach the research team and initiate enrollment on their own behalf. In such cases the enrollment and consent process should not be conducted by the investigator, but should be conducted by someone on the research team who is at "arm's length" to the potential participants whenever possible.

Convenience sampling may also be approved by the IRB in cases where the IRB determines that 1) the study qualifies as no greater than minimal risk; 2) adequate steps have been taken to minimize potential coercion; and 3) any harms that may arise in the research would not be exacerbated by the academic or employment relationship.

Waiver of Prohibition Against Requiring Enrollment in Educational Research

The IRB can waive the prohibition against requiring student participation in educational research on a case-by-case basis when an investigator can demonstrate that participation is educational and integral to fulfilling course requirements or that full class participation is essential for study integrity or when the study qualifies for exemption under 45CFR46.101(b)(1).

Recruitment Through the Psychology Subject Pool

Studies intending to recruit students in Introductory Psychology must conform to both IRB and Psychology Subject Pool requirements. The Psychology Subject Pool Committee requires that the proposed research be educational for the students and consistent with course goals.

Additional consent requirements are required by the IRB, including clearly indicating the ability to meet course requirements in other ways as agreed to between the IRB and the Psychology Subject Pool Coordinator. Note that approximate 6% of Yale freshmen and freshmen are minors and parental consent is required unless eligible for waiver under IRB policy 310.

Recruitment of non-Yale Students or Employees

Yale investigators seeking to recruit students or employees from another institution for participation in Yale research must respect the institution's policies or practices with regard to such recruitment and seek appropriate institutional permission before initiating recruitment Activities.

Related Information

Policy 410: Recruitment of Research Participants

Policy 400: Confidentiality of Information

Procedure 410 PR.2: Recruitment Time Frames and Settings

Contacts

Subject	Contact	Phone
Biomedical Research involving students or employees at YSM	Human Investigation Committee	785-4688 ysmhic@yale.edu
Research involving students or employees at YSN	Human Subjects Research Review Committee	737-2420 nursing.yale.edu/ Research/Oversight
Behavioral and Social Science Research involving students or employees	Human Subjects Committee	436-3650 human.subjects@yale.edu
Use of the Psychology Pool	Psychology Pool Coordinator	Psychsubject.pool@yale.edu

Roles and Responsibilities

[Human Investigation Committee](#)

The HIC I and HIC II serve as the two Institutional Review Boards or IRBs for biomedical human subjects research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

Human Subjects Research Review Committee

The HSRRC serves as the IRB for all research involving human subjects that is conducted by faculty and students at the Yale School of Nursing.

Psychology Subject Pool Coordinator

The psychology subject pool coordinator oversees the process for ensuring that research proposals intending to recruiting introductory psychology students meet education standards set for the course.

Institutional Official

The Deputy Provost serves as Institutional Official for Yale University. As such, the Institutional Official is responsible for ensuring that Yale fulfills the obligations and responsibilities promised in the terms of its Assurance.