IRB Policy 350  Participation of Yale Students, Fellows, Trainees or Employees in Research

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. This policy does not apply to projects that incidentally recruit Yale students, fellows, 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 undue influence 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. Similarly, potential participants in a subordinate position to an investigator may feel undue pressure to participate in research. Researchers must acknowledge that recruiting their own students, fellows, trainees or employees 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 student, fellow, trainee or /employee 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 in the research.

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

Postgraduate fellows are not University employees. They hold a terminal degree other than a doctorate and conduct advanced study with a designated faculty supervisor under an appointment for a maximum term of one year.

Postdoctoral fellows are not University employees. They are appointed by or affiliated with a department or other academic unit to extend their education and professional training up to four years. They are typically 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.

Visiting fellows are neither members of the faculty, nor Yale employees, and they receive no compensation from the University.

(Definitions excerpted from the Yale University Faculty Handbook)

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

350.1 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.

350.2 Students as Research Subjects
Investigators enrolling their own or their institution’s students or trainees in research must:

- Not directly interact for recruitment purposes with students, fellows and trainees who report directly to the investigator unless one of the special situations applies (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.
- 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 students will not be subject to undue influence or coercion and to ensure that each student’s privacy will be respected.
350.3 Employees as Research Subjects
Investigators enrolling their own or their institution’s employees in research must:

- Not directly interact for recruitment purposes with employees that report directly to the investigator unless one of the special situations applies (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 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 online or 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.

350.4 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 Institutional Review Board (IRB) is not required when the University is not engaged in the research as defined in IRB Policy 100: IRB Review of Research Protocols.

Special Situations/Exceptions

Permitted Convenience Sampling
While convenience sampling of an investigator’s own students or staff is generally prohibited of the investigator, students or staff 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 or undue influence; 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 45CFR §46.101(b)(1): Educational Research.

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 freshwomen are minors and parental consent is required unless eligible for waiver under IRB Policy 310: Participation of Children in Research.

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
IRB Policy 410: Recruitment of Research Participants
IRB Policy 400: Confidentiality of Information
410 PR.2: Recruitment Time Frames and Settings

Contacts

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<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research involving students or employees</td>
<td>Human Investigation Committee or Human Subjects Committee</td>
<td>203.785.4688 <a href="mailto:ysmhic@yale.edu">ysmhic@yale.edu</a> <a href="mailto:human.subjects@yale.edu">human.subjects@yale.edu</a></td>
</tr>
<tr>
<td>Use of the Psychology Pool</td>
<td>Psychology Pool Coordinator</td>
<td><a href="mailto:Psychsubject.pool@yale.edu">Psychsubject.pool@yale.edu</a></td>
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Roles and Responsibilities
Human Research Protection Program (HRPP)
The Human Research Protection Program is responsible for the oversight of human research protection through ongoing education, monitoring and evaluation of all parties involved in the conduct of human research.
Human Investigation Committee (HIC)

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

Human Subjects Committee (HSC)

The HSC serves as the Institutional Review Board for social, behavioral and educational human research at Yale University.

Psychology Subject Pool Coordinator

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

Revision History: