



RECRUITMENT OF STUDENTS, EMPLOYEES, FRIENDS, AND FAMILY MEMBERS AS RESEARCH PARTICIPANTS

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This policy describes the responsibilities of the DUHS IRB and Duke Investigators when recruiting and enrolling students, employees, including work colleagues, friends, and family members as participants in research conducted under the DUHS IRB's jurisdiction.

The federal regulations do not specifically mention the inclusion of students, employees, friends, and family members in research, but their designation as a special population stems from 45 CFR 46.111(b):

“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

This regulation does not prohibit the inclusion of students, employees, friends, and family members in research, or provide specific criteria for inclusion. Published OHRP guidance, while allowing the possibility of enrolling these individuals, emphasizes the need for carefully considering whether their inclusion can be justified since the investigator's, or any other study team member's, relationship with them is potentially coercive.

I. Students and Employees, including study team members

Recognizing that a potential for coercion exists when an employer or faculty member recruits a subordinate to participate in a research study or wishes to enroll in a subordinate's research study, the DUHS IRB routinely does not approve proposed research in which investigators will enroll students or employees with whom they have, or can reasonably anticipate having, a supervisory relationship.

The IRB will consider the inclusion of these individuals in research if the investigator has proposed adequate methods and guidelines for recruitment and participation to minimize coercive elements and risks to privacy and confidentiality.

II. Friends and Family Members

Likewise, the IRB must receive appropriate assurances that the investigator has minimized coercive elements and risks to privacy and confidentiality for this group as well.

As a rule, the IRB disapproves of recruiting employees, students, friends, or family members as a targeted population, merely for the sake of convenience or because of their easy availability.

Research participants should be recruited through general announcements, social media postings, web site, newspaper, or other advertisements, rather than individual solicitations.

Investigators seeking to target students and employees, including study team members, for enrollment must describe in their IRB application how they will avoid creating the perception that participation in the research by a student or employee will favorably influence the participant's professional or academic career. Investigators must stress that the student/employee's performance evaluations, job advancement, or grades will not be influenced by participation or lack of participation in the research study. As appropriate, the IRB may require language to that effect in the informed consent document.

In keeping with accepted policy on the Duke University campus that allows students to participate in research and obtain credit in their courses for their participation, the DUHS IRB will consider that practice when reviewing a research study proposed by a Duke University campus investigator. Any such research involving patients and/or utilizing an FDA-regulated product or medical procedure or a medical imaging device is forwarded to the DUHS IRB for review.

III. Obtaining IRB Approval for Study Participation

Any investigator wishing to enroll one of the groups discussed in this policy must obtain specific IRB approval for their inclusion. The following elements must be discussed in the research summary, for initial reviews, or in an amendment for an ongoing study:

- Precise description of the group or individual(s) to be enrolled;
- Relationship of the group or individual(s) to the study team, including supervisory relationships;
- Importance of including this group or individual(s) in the study;
- Who will consent the group or individual(s) and how the possibility of coercion will be minimized; and
- Process for ensuring objective analysis of study results, particularly for friends and family members.