

Investigator Guidance Series

University of Utah Institutional Review Board

RESEARCH INVOLVING STUDENTS

Federal Research Regulations

Students are not directly mentioned in the federal regulations as a vulnerable population. However, the University of Utah IRB considers students to be a vulnerable population because students may be vulnerable to coercion or undue influence. The regulations state:

“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”^[45 CFR 46.111(b) and 21 CFR 56.111(b)]

If students are involved as research participants, the investigator must include additional safeguards in the study to protect their rights and welfare.

Description

Student participation in research is common on university campuses. Of particular concern is the possibility that students may feel pressure to participate in research. Students may feel they must volunteer to participate to win favor with faculty (e.g. participating in research may lead to a better grade or a letter of recommendation, etc.). Students may also feel that if they choose not to participate it will negatively impact their relationship with faculty.

The University of Utah IRB recognizes the importance of students participating in research and does not prohibit students from voluntarily participating in research. The following guidelines have been implemented to protect students and minimize coercion while allowing students to voluntarily participate in research.

Course Credit for Research Participation

Often in behavioral or social science classes, course credit is offered for participation in research. If participation in research is required in a class, students must be given other options for fulfilling the research requirement. Other options must be comparable in terms of time, effort and educational benefit. For example, to fulfill the research requirement, students can choose to participate in two hours of research, read research articles and answer questions, or attend a faculty research symposium. To reduce coercion, the questions about the research articles are not graded, and students who attend the symposium are only required to be in attendance to receive research credit.

Students cannot be required to participate in one particular study to earn course credit. Students must have the freedom to participate in a study of their own choosing.

Students cannot be required to participate in research that is greater than minimal risk (as determined by the IRB) to earn course credit.

Right to Withdraw

If a student agrees to participate in a study, he/she may withdraw from the study at any time without losing credit. The right of the student to withdraw must be presented in the consent process and informed consent document.

Advertisements

An investigator must recruit participants generally rather than from those students enrolled in a course taught by the investigator or others involved in the study. For example, advertisements should be posted in a general area in the school or department. Advertisements must also adhere to the University of Utah IRB policy regarding recruitment (see Investigator Guidance Series: Recruitment Methods and Advertisements).

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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Additional Considerations

Confidentiality

The University setting may provide opportunities to conduct research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol. This type of research may present confidentiality risks particularly in the close environment of the university setting. Participants should be made aware of these risks in the consent process and the informed consent document.

Age of Consent

Individuals under the age of 18 are considered children (exceptions are described in the Investigator Guidance Series: Research Involving Children) and are subject to additional regulatory protections. Generally, children are required to have parental permission and provide assent before participating in research. Investigators need to consider that some university students are not 18 years old and cannot provide consent to participate in research without first obtaining parental permission.

Student-Athletes: Compensation for Participation

It has become common for institutions to use student-athletes in studies specifically related to the conditions under which student-athletes participate. Such research is important but must be balanced with protecting the student-athletes' eligibility to participate in collegiate sports.

Providing compensation to student-athletes for participation in research studies is allowed according to the following guidelines:

- Student-athletes may receive compensation for participation in studies that involve both student-athletes and non-athletes, provided they receive the same compensation.
- For research studies involving **only** student-athletes:
 - Student-athletes may receive compensation from the Association for participating in specified NCAA research studies, provided the compensation is consistent with the compensation offered in studies involving non-athlete populations.
 - Student-athletes may receive compensation for participating in a research study involving only student-athletes, provided the study is initiated and conducted by a faculty member; and the study and compensation arrangements are approved by the IRB consistent with its policies applicable to other non-athlete research studies.

The IRB may approve research involving student-athletes provided the study does not violate any NCAA rules or regulations or jeopardizes a student-athlete's eligibility. The IRB may consult with the NCAA Faculty Athletics Representative as needed.

Points to Address

New Study Application:

1. **Section 3.3, Vulnerable Participant Groups:** Select "Students, staff, or faculty of the research institution.

2. **Vulnerable Populations Page:** Complete all the sections on this page as they apply to students as a vulnerable population.

Consent Document:

1. **Alternative Procedures:** If course credit is given for participation in research, describe alternatives to taking part in the study.

2. **Voluntary Participation:** State that the decision to withdraw from the research will not involve a penalty and, if applicable, that course credit will not be taken away as a result.

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3. **Compensation:** Describe how much course credit will be given for participation, if any.

References & Links

*OHRP IRB Guidebook:
Students, Employees,
and Normal Volunteers*

http://www.hhs.gov/ohrp/irb/irb_chapter6ii.htm#g11

*Investigator Guidance
Series: Recruitment
Methods and
Advertisements*

http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

*Investigator Guidance
Series: Research
Involving Children*

http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

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