DISCLAIMER: This document has not been updated to reflect regulatory changes effective January 21, 2019.

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 15: Informed Consent, Enrollment, and Other Considerations for Research Involving Cornell Students

1. Subject of Policy & Procedure

This document sets forth the requirements for obtaining IRB approval for research involving Cornell University students. Student is defined as any individual who is enrolled in a graduate, undergraduate, or training program of Cornell University.

There are no federal regulations that specifically address the inclusion of students in research protocols. However, these participants are vulnerable to being unduly influenced by the expectation that participation or non-participation in a protocol may place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community).

They may also be vulnerable to undue influence to participate from being approached multiple times for participation in research because their presence on campus makes convenient their recruitment and participation as controls. Confidentiality and security of data also may be of special concern to potential student participants, especially in light of the closeness of the university community.

The IRB, therefore, will pay special attention to ensuring that the research protocol and associated recruitment methods and informed consent avoid coercion or the appearance of coercion when including Cornell students in research.

While special attention by the IRB is warranted, students have the same rights as any other potential participants to participate in an IRB-approved protocol, regardless of the degree of risk.

Finally, certain Cornell students may be members of another vulnerable population (*e.g.,* pregnant students, students who are under the age of 18, *etc*.). In these instances, the Protocol PI and the IRB should carefully apply, as appropriate, not only this SOP, but also the SOPs pertaining to the additional vulnerable populations of which the Cornell student is a member.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell faculty, staff, or students or by anyone conducting a research activity supported by Cornell or on property maintained by Cornell.

3. Terms and Definitions

All parties to whom this policy applies (*e.g.,* faculty, students, staff, IRB members) should consult the IRB Glossary at http://www.irb.cornell.edu/glossary/.

4. See Also

Affected researchers and students should also consult:

1. Cornell University Federal Wide Assurance Registration: http://www.irb.cornell.edu/regulations/fwa.htm

5. Regulations Applicable to Informed Consent

5.1. The Belmont Report
5.2. 45 CFR 46.109(b), (c), & (e): IRB Review of Research, stating that (1) "[a]n IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;" (2) "[a]n IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117;" and (3) "[a]n IRB shall have the authority to observe or have a third party observe the consent process and the research."
5.3. 45 CFR 46.111(a)(4), (a)(5), & (b): Criteria for IRB approval of research, mandating that (1) informed consent "will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116," and "appropriately documented, in accordance with, and to the extent required by §46.117;" and (2) "[w]hen 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."
5.4. 45 CFR 46.116: General requirements for informed consent
5.5. 45 CFR 46.117: Documentation of informed consent

6. Requirements for IRB Approval of Research Involving Cornell Students

6.1. Recruitment—Protecting Against Coercion

- A Protocol PI may offer extra credit as an incentive to students to participate in a research project. The amount of such credit, however, cannot be so significant so as to be coercive. This limitation on extra credit applies to an amount offered from an individual study as well as the aggregate amount of extra credit offered for a particular course. Investigators are discouraged from directly recruiting individuals they supervise or selecting participants on such basis.

- To avoid the appearance of coercion, the IRB may elect to require that the Protocol PI take one or more of the following measures:

    - To offer the same amount of extra credit for non-participating students who complete an assignment requiring equivalent time and effort such as a short paper or presentation or attendance at a research colloquium.

    - To advertise for subjects generally (*e.g.*, through notices posted in the school or department) rather than to recruit individual students directly or individually.

- To allow students to withdraw from participation at any time without losing the extra credit.

- To give students several studies to choose from, rather than requiring them to volunteer for a particular study, especially where participation is a course requirement.

- To provide justification for including student volunteers from courses for which they are the instructor.

- To indicate that the extra credit will not be made part of the grading curve, but will be taken into account for each individual.

- In light of the limited financial resources of most students, Protocol PIs should be cautious about offering excessive monetary compensation to students. The IRB may deem that other incentives such as limited free food are more appropriate.

6.2. Informed Consent

- The IRB may need to give special consideration as to who is responsible for obtaining consent from students, in order to avoid the appearance of coercion by a faculty member of a student.

- Depending on the risk level of the project, the IRB may consider whether a member of the IRB, ORIA, or some other third party affiliated or unaffiliated with Cornell should observe/monitor the consent process

6.3. Confidentiality of Data

- The IRB may require extra precautions to ensure the confidentiality and security of data files for Cornell participants. As with research involving human subjects generally, IRBs should be aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible.

- Because Cornell is a relatively closed community, the IRB may also require that the data collection process be designed to be equally sensitive to the privacy of individuals. For instance, a study on sensitive topics as described above should not have participants waiting in a public space where fellow students may readily deduce their participation in the study.

6.4. Administrative Approval

- In addition to the IRB, the Dean of Students or his or her designee must approve research projects where Cornell students are the focus of the research, *per se*. The Dean's approval is not required where the focus of the research is not Cornell students, such as when students may be included in the research out of coincidence or convenience but are not a target population.

- Similarly, if a Protocol PI seeks to target students in a specific college for recruitment (*e.g.*, Human Ecology, CALS), the college dean's approval of the project is required.

- Where the university will facilitate recruitment of students (*e.g.*, use of mass email to the student body), approval from the University Registrar is also required.