

COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD

GUIDANCE ON THE INVOLVEMENT OF STUDENTS AS RESEARCH PARTICIPANTS

I. BACKGROUND

Students matriculating at Columbia University (**Columbia** or the **University**) often participate as research subjects in studies conducted by faculty, instructional staff and other researchers. In some research situations, the participation of students is integral to the aims of a research protocol. In other cases, researchers recruit students in studies because of their accessibility to the researchers and the convenience of recruiting on campus.

Under federal law and regulations, legally effective informed consent must be obtained from every individual, including students, prior to participating in any research project, unless the research is exempt from Institutional Review Board (**IRB**) review or the IRB has approved a waiver of consent. In obtaining informed consent, federal regulations (e.g., 45 CFR 46.116) explicitly provide that investigators should seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence (e.g., 45 CFR 46.116). See the [Columbia University Institutional Review Board Policy on Informed Consent](#) for further information on the requirements for informed consent in human subjects research.

Because of their status, students may be open to coercion or undue influence in research studies, particularly from faculty members who are teaching courses in which they are participating. They can be seen as “captive participants” due to the inherent power differential between students and teachers in terms of knowledge and skills in the applicable discipline and the desire of students to attain specific goals in the course. Coercion may occur when there is an overt or implicit threat of negative consequences to obtain the student’s cooperation. For example, a researcher might inform a prospective subject that participation in a study is required to have access to certain educational services. Undue influence may occur when a researcher presents an excessive or inappropriate reward to a prospective subject, such as indicating that extra credit may only be obtained if they participate in the research.

Because the involvement of students as research participants depends to some extent on the nature of the research and the standards of the particular discipline in which the research is conducted, this Guidance will set forth a set of recommendations of the University’s Human Research Protection Office (**HRPO**) that should be considered by the University’s schools, institutes or departments (each, a **University Unit**) in fashioning more specific guidelines for their researchers. However, any such University Unit’s guidelines must be consistent with the principles articulated in this Guidance.

II. Effective Date

The Effective Date of this Guidance is February 15, 2024. This Guidance supersedes the University's Policy on the Use of Columbia University Students as Study Subjects in Research, dated June 26, 2003.

III. Guidelines

A. General

This Guidance is applicable only to studies in which students are participants because of their status as students and not to studies in which their status as students is either inapplicable or only incidental to the study.

Studies that target students as research participants should involve no more than minimal risk. This includes studies for which only students will be subjects, and studies that utilize recruitment methods designed specifically to interest students. Students may decide to enroll in a greater than minimal risk study when their status as a student is incidental to enrollment.

Projects must be approved by the IRB unless the research is exempt from IRB review or the IRB has approved a waiver of consent, or the project is deemed to be a quality improvement (**QI**) project rather than research. See the [Columbia University IRB Guidance for the Classification of Quality Improvement Activities versus Research with Human Subjects](#) for additional information.

B. Recruitment

In general terms, solicitation of student participants in research studies must be done in a non-coercive manner. The pressure to participate might be perceived rather than actual, but it can be present nonetheless. Students, if they refuse to participate, might anticipate possible risks to future relationships with faculty and fear repercussions, such as lower grades, fewer learning opportunities, lower evaluative outcomes or slower progress in learning.

The most coercive situation is either required participation as a course requirement or direct solicitation by a faculty member who is teaching a course in which the student is registered. As a general rule, faculty should employ their own students as participants only when those students are essential to address the specific research question, as in issues of program evaluation or pedagogy. In any case, prior to enrolling in a course, if practicable, students should be informed of the possibility that they may be asked to serve as research participants in studies under the direction of the faculty member. Rather than being approached by a member of the faculty in person or by written communication, participants can be recruited by a general announcement or central posting mechanism. Use of subject pools permits the students to voluntarily sign up for studies in which to participate.

To avoid direct pressure on their current students, if possible, faculty can seek participants among students for whom they do not have direct teaching relationships. Recruitment by an independent third party so that the instructor does not know who participated in the research is another approach.

Justification is required if extra credit in a course is given to students who participate in research, and students should be given other alternatives for earning the credit, such as writing short papers or book reports, completing additional readings, participating in research seminars or completing a similar project. In general, the alternatives to participation should be comparable in terms of time, effort and educational benefit. Penalties or credit deductions may not be applied if a research subject chooses not to participate in, or to withdraw from, a study.

Independent recruitment is generally not possible in pedagogical studies in the discipline in which courses are given or program evaluations of courses in which the student participant is involved. However, the scientific basis for pedagogical and curricular strategies can often only be developed by research. If there is a course requirement that students serve as research participants in studies conducted by faculty members, alternative ways must be provided for students to meet the requirement. Before the solicitation begins, students should receive a written description of the various ways to meet the requirement.

C. Consent

In general terms, federal regulations require that appropriate informed consent be obtained from each research subject. When obtaining informed consent, researchers must inform participants about (1) the purpose of the research, its expected duration and procedures; (2) their right to decline to participate and to withdraw from the research once it has begun and any consequences of declining or withdrawing; (3) any potential risks, discomfort or adverse effects; (4) any incentive for prospective benefits of participation; and (5) any limits on confidentiality. Discussion of the risks and benefits of a study prior to the participant's enrollment is essential. These requirements apply to studies with student participants. In addition, students need to be fully informed as to whom will have access to the research data, as the answer to this question can impact the student's understanding of how the researcher intends to maintain privacy and confidentiality, and the level of risk that the student may be subject to in the project.

In addition to being provided with the above information and consent forms, students should also be provided with the information on how to contact the HRPO if they feel coerced at any time during the consenting process.

D. Privacy and Confidentiality

Research with students, particularly when the study involves interviews, observations or self-descriptions in documents, may involve risks to the students. Revealing personal data to a professor might put students in a position of acute discomfort or could even involve undue risk. It is necessary to ensure that data collected are unaffected by the power relationship between student and the faculty member. Research involving disclosure of information the participants may view as personal or sensitive should be conducted in a private setting. If possible, the

employment of research assistants in collecting data may help in minimizing such risks. Identifiable data collected during the study can then not be made available to the faculty member until after grades in the course have been submitted so that the potential for the evaluative effect of participation or non-participation no longer exists. The identity of student participants can also be coded by a honest broker or other independent third party and kept separate from the research data.

In addition, data can be collected and made anonymous by an honest broker or other independent third party prior to faculty analysis to maintain student confidentiality. Anonymity also may produce better quality data, as students might provide some data to please their teachers or may modify responses to avoid embarrassment if their responses are not anonymous. In qualitative research where quotations from student data might be used to support findings or in a study where the number of participants is limited, researchers must report their findings in such a way that the identity of participants is not discernable. Identifying details from qualitative data can be replaced with generic descriptors to present disclosure of participants' identity without changing the inherent substantive nature of the data.

Including a student's work product in a research project is subject to the requirements set forth in Section E below. The same is true when a researcher wishes to quote, paraphrase or report on unpublished writing of a student or when reporting on oral statements made by a student in private or via video, audio or photography.

E. FERPA

The Federal Family Educational Rights and Privacy Act of 1974, as amended (**FERPA**) (34 CFR 91), which is applicable to the University, sets forth requirements for the protection of the privacy of student education records. Under FERPA, the term **Education Records** is broadly defined as "those records (1) directly related to a student and (2) maintained by an educational agency or institution or by a party acting for the agency or institution". Education Records include, but are not limited to, grades, transcripts, surveys, course work product, class lists, course schedules, financial information and student discipline files. Use of Education Records for research is subject to FERPA. Specific information, called **Personally Identifiable Information (PII)**, is subject to additional protections. Information is deemed to be PII if it contains the student's name, address, social security number, date or place of birth, mother's maiden name and any other information that would allow a reasonable person in the school community to identify the student with reasonable certainty. FERPA gives students certain rights with respect to their education records, including, among other things, the right to consent to any disclosure of PII from such records.

The University's general policy is not to permit access to, or release of, educational records or PII contained therein without the written consent of the student. See the Columbia University Policy on Access to Student Records under the Federal Family Educational Rights Under FERPA [<https://universitypolicies.columbia.edu/content/federal-family-educational-rights-and-privacy-act-ferpa>] (the **FERPA Policy**). Under FERPA, such consent must specify the records or data that may be disclosed and the purpose of the disclosure and the party or class of parties to whom

the disclosure may be made. Note that the requirements for a FERPA consent are not the same as those required by the IRB for informed consent.

FERPA does permit the disclosure of information from an Education Record without prior consent of the student to officials within the University whom the University has determined to have a legitimate educational interest in obtaining the data. The FERPA Policy provides that access will be granted if the official needs such data to fulfill their professional responsibilities. However, it is within the University's discretion to determine what is a legitimate educational interest and whether student privacy interests outweigh such interest.

F. Letters of Support for Research Projects Involving Students

The HRPO requires that an IO (**Affiliate IO**) of the University approve research projects that propose to enroll Columbia affiliates, including students. A letter of support from the University Unit in which students are being recruited for such projects should be signed by the Affiliate IO and attached to the protocol submitted for IRB review. The HRPO is responsible for routing the letter of support and description of the project to the applicable Affiliate IO for review. In this context, the Affiliate IO is the individual who is the signatory on the applicable Federalwide Assurance.