

**COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
POLICY
STUDENTS AS RESEARCHERS**

I. SCOPE:

This Policy applies to all human subjects research conducted by students at Columbia University (“Columbia”) and clarifies which research projects or activities require review by the Columbia Institutional Review Board (IRB) for the protection of human subjects in research.

II. EFFECTIVE DATE: March 16, 2012

III. BACKGROUND:

All federally-supported or conducted activities constituting human subjects research must be reviewed by an IRB prior to initiation of the research in accordance with regulations of the Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 56) (collectively, the “Regulations”) unless such research activities are exempt from review pursuant to 45 CFR 46.101(b) and 21 CFR 56.103(b) (“Exempt Research”). It is Columbia’s policy that such requirements apply to all human subjects research, whether or not federally-supported, including research by students, and that research that may constitute Exempt Research must also be submitted to the IRB for a determination that such research should in fact be considered exempt.

Human subjects research is defined as follows: “Research”: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. “Human subject” is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

The process of learning about and practicing research methodology (i.e., pedagogical research) may require student investigative activities that involve humans but do not, under the Regulations, require IRB review because such activities do not fall within the federal definition of Research (as defined above). Recognizing that some pedagogical research activities may present more than minimal risk of harm to participants and considering the relative inexperience of students in applying research methods, **Columbia requires submission of some student projects that do not meet the federal definition of Research**, in order to protect the subjects in such activities. For the sake of clarity, Section IV.A. of this Policy articulates the criteria of projects that do not have to be submitted for review. All student projects that involve humans and do not meet such criteria must be submitted for IRB review.

IV. POLICY:

Except as provided in section IV.A. below, all research activities involving human subjects and conducted by Columbia students must be approved by the IRB prior to the initiation of the research activity. This Policy applies to human subjects research activities that are broader than those defined in the Regulations and includes classroom activities that may not be considered Research, but may involve greater than minimal risk to subjects.

In the case of student course-related research projects, it may be difficult at times to distinguish between those that require IRB review, and those that are designed simply to learn and/or practice research methodology. The IRB has established the following guidelines for determining when IRB review is necessary for projects that are related to an academic course or program.

A. Low Risk Introductory Research Methodology Exercises (No IRB submission required)

Student projects that are designed solely to provide students with an opportunity to learn or practice research methods do not require IRB review if they meet **all** of the following criteria:

- (1) take place in a classroom, department, dormitory, or other campus setting, or in a public setting with generally unlimited access to the public, such as a shopping center, park, or street;
- (2) involve only the learning of research techniques and are not designed to potentially advance the literature;
- (3) involve **no** more than minimal risk to subjects (Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests); and
- (4) utilize anonymous collection of data (i.e., with no names, social security numbers, or other direct identifiers; and without codes that can be linked to a list of names; and including no indirect identifiers or information that when combined would allow identification of the subject).

Research conducted over the internet will not be permitted under this category.

B. Research Projects, Directed or Independent (IRB submission required)

Any research conducted by students that involves human subjects but does not constitute a research methodology exercise or practicum, as characterized in Section IV.A. above, must be reviewed by the IRB. This includes, but is not limited to, all undergraduate and graduate research projects whether or not conducted to fulfill course or degree requirements, undergraduate senior, undergraduate honors, or masters' theses, and doctoral dissertations.

Research projects are either "Exempt Projects" or "Non-exempt Projects".

1. Exempt Projects:

Student projects that constitute Exempt Research must be submitted to the IRB for determination that they are eligible for exemption.

A complete listing of the federal exemption categories is attached as [Appendix A](#) and is also available online at:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101>

When all students in a class are using similar methods of recruitment and data collection, in the same or similar projects that are no more than minimal risk to subjects, the instructor may submit a proposal to the IRB for determination that all such projects are exempt, rather than requesting such determination on a project by project basis.

2. Non-exempt Projects:

All non-exempt student research projects must be submitted individually for IRB review.

Non-exempt projects that are minimal risk will require either review by an experienced member of the IRB (“Expedited Review”) or review by a convened IRB (full Board review).

To be eligible for an Expedited Review, the research must involve: a) no greater than minimal risk to subjects; and b) procedures that fall into one or more of the categories of research identified as eligible for Expedited Review by the Regulations.

A complete listing of the federal expedited review categories is attached as [Appendix B](#) and is also available online at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

Projects that are neither Exempt Research nor eligible for Expedited Review must be evaluated at a convened meeting of the IRB. In such cases, the protocol must be submitted sufficiently in advance of an IRB meeting to be added to the agenda and distributed for in-depth review prior to the meeting. For assistance in planning submissions, IRB meeting dates are posted on the Columbia IRB websites (click on “About the HRPP/IRB”; links to home pages are provided at the end of this document).

C. Responsibility of Faculty Advisors for all Student Research Projects

Columbia’s policy requires that, unless an appropriate waiver is obtained, the individual who is named as Principal Investigator (“PI”) on a research project must have a particular academic or research ranking in accordance with Columbia policy. No student researcher may serve as the PI on a protocol that is submitted for IRB review; however, he/she should be named as a co-investigator.

Faculty advisors as well as student researchers must complete required training before conducting research with human subjects (or serving as a PI on student research projects). The training is available online; course details and specific instructions may be found on the

Columbia IRB websites at:

<http://cumc.columbia.edu/dept/irb/education/index.html#Required%20Training>

It is the responsibility of the faculty advisor to determine when a student project that is conducted to fulfill a course requirement does not meet the definition of a research methodology exercise or practicum and must be reviewed by the IRB. Advisors should be familiar with relevant regulations and policies so that they may guide students in selecting the topic of their research project, and assist in preparing review materials for the IRB. In addition, the advisor and student have a shared responsibility to ensure that all research activities, whether research methodology exercises or practica, exempt projects, or protocols that have received IRB approval (whether expedited or full Board), are conducted according to the approved protocol and the ethical standards of the relevant discipline.

D. Responsibility of Students for all Student Research Projects

It is the responsibility of the student researcher to conduct the study in accordance with the IRB-approved protocol. Any change to the research must be submitted for prospective IRB approval prior to implementation. If a change is necessary to minimize or avoid harm to currently enrolled subjects, and there is no time to obtain IRB approval, such a change should be implemented immediately by the researcher. Even in this latter situation, a modification must be submitted as soon as possible to the IRB.

Students must also ensure that the research study maintains a current IRB approval. The PI of the study must submit the protocol for re-approval by the IRB at least 60 days prior to the expiration of IRB approval, if such research will continue beyond the expiration date. Once IRB approval expires, all research activities must cease until re-approval has been granted by the IRB.

Students must keep their advisors informed of the progress of the research and any harm(s) that may occur to human subjects as certain harms or increased risks to subjects must be reported to the IRB in accordance with the [Reporting of Unanticipated Problems](#) policy. When the study has been completed, or if the student will complete his/her relationship with Columbia and Columbia will no longer be involved in the research, the student must ensure that a [“Termination”](#) has been submitted to the IRB in RASCAL.

Columbia IRB Websites

CU-MS IRB: <http://www.columbia.edu/cu/irb/>

CUMC IRB: <http://www.cumc.columbia.edu/dept/irb/>