

Student Research Guidance

Research as defined in the 45 CFR 46 and conducted by graduate and undergraduate students at the Columbia University Morningside Campus is subject to federal regulations which require that all research protocols involving human subjects be reviewed by an Institutional Review Board for the protection of Human Subjects in Research (IRB). However, these regulations allow certain types of course-related studies to be conducted without IRB review.

Research and Clinical Practica

Research and clinical practica (usually in the form of course-related research or evaluation projects and/or directed studies) are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis. Typically such projects are quite limited in scope, do not lead to generalizable knowledge, and are not undertaken with that goal in mind. For example, a student may interview a peer when the interview does not involve any sensitive, personal information.

Such projects should not put the subjects at more than minimal risk, and the data must be recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises" and are not subject to review by the IRB. They do not require review unless the student researcher anticipates publishing the results or presenting at a professional meeting.

Research Projects, Directed or Independent

Any research conducted by students, graduate or undergraduate, that does not fall under the definition of a research or clinical practicum, which uses human beings as subjects, and which is intended to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations.

Recognizing the time constraints imposed on projects that must be begun and completed within a single semester, the IRB will make every effort to work with instructors to process proposals promptly. However, instructors must plan for and allow adequate time for the review process to occur (approximately a week to a month, depending on the particular human subjects issues raised by the proposed research). The later in the term a proposal is received, the more difficult it will be to accomplish the review in time for the projects to be completed during the current semester. It is very strongly urged that instructors submit proposals within the first three weeks of the semester for projects that must be completed during the current semester. In some cases, when students in a course are all using similar methods of recruitment and data collection, instructors may submit an aggregate proposal. Student research projects may be submitted to the IRB for

consideration as exempt research if they meet federal exemption criteria such as research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior in which data is collected anonymously (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names) or otherwise qualifying under exemption category 2 of the federal regulations. The course instructor must submit exemption requests to the IRB.

See the following link for a complete listing of the federal exemption categories:
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101>

All non-exempt student research projects must be submitted for regular IRB review. Keep in mind that all requests for review of non-exempt projects must be submitted two weeks before the next scheduled IRB meeting if the project requires full review by the IRB. IRB submission deadlines are posted on line at:
<http://www.columbia.edu/cu/opg/policies/hsmeeting.pdf>

Responsibility of Student Advisors for all Student Research Projects

Faculty advisors of both undergraduate and graduate students must be certified to conduct research with human subjects, even if they are not currently conducting research with human subjects. The current way of receiving certification is to complete the Computer-Based Training (CBT) program available at the NIH website: <http://cme.nci.nih.gov/>

It is the responsibility of faculty advisors to determine when an undergraduate or graduate student project does not meet the definition of a practicum and must be reviewed by the IRB. However, the advisor must be certified as noted in the previous bullet to be authorized to make this decision.

It is the responsibility of faculty advisors to ensure that research practica and exempt research activities are conducted according to the ethical standards of the relevant discipline.

When student research activities are not practica, it is the responsibility of faculty advisors to assist students in preparing review materials for the IRB and to ensure that the research is conducted in accordance with CU's agreement with the federal government and with applicable CU policy.

Potential Practicum Problems

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and subjects that raise concerns for the well-being of the subjects and students themselves. Projects collecting data about illegal activities, those which could cause emotional distress in the subjects, those which would place the

students at risk if confidentiality were breached, and those with children as subjects need to be constructed with special care.

While practica are not under the purview of the IRB, the staff of the IRB are available for consultation with students and for class presentation regarding issues of the protection of the rights and welfare of human subjects. It is important to note that data collected as practica cannot at a later date be used for presentation at conferences, publications, or doctoral dissertations.