

Guidance Document: Student/Classroom Research Projects

Background

The University of Colorado Boulder (CU-Boulder) requires that all research involving human subjects conducted by faculty or staff affiliated with the university be reviewed and approved by the Institutional Review Board (IRB) prior to initiation. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB.

The IRB further requires that all student research activities are supervised by a faculty member; however, some types of student research activities may not require IRB review above and beyond faculty supervision. CU-Boulder supports a wide range of both undergraduate and graduate student research projects using human subjects -- from course-related research exercises to dissertation studies. This document is intended clarify IRB policy and procedures as they relate to student and classroom research projects.

What does "Classroom Research Project" mean?

Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research, but are not designed to develop or contribute to broader, generalizable knowledge, do not meet the federal definition of research and are therefore generally not subject to (i.e., is excluded from) IRB review/approval.

Curriculum-based projects in which students conduct research-like activities involving human subjects need not be reviewed by the IRB if the following conditions are satisfied:

- The project involves minimal risk to subjects. Minimal risk means "that 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." (45CFR46.102(i)).
- The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed (see Footnote A).
- The project does not involve persons from vulnerable populations as participants (see Footnote B).
- The project must involve the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher. Though not required, it is recommended that instructors/students consider providing a consent document to participants and fully informing them of the research they will be taking part in.
- The results of the project will never be distributed outside the classroom and/or institutional setting or used for publication, although the results may be presented to instructors or peers for educational purposes or as part of a class assignment. If the possibility exists that either the instructor or the student would consider disseminating the data as generalizable knowledge, the research must be submitted for IRB review. If after collection of data the instructor or student deems the results to represent generalizable knowledge worthy of dissemination, the investigator should immediately submit a protocol describing the method and results to the IRB for review/approval. Please note that approval under such circumstances is not guaranteed and any data collected under a classroom projects exclusion may not be disseminated prior to IRB approval.

Who is responsible to oversee Student Projects/Classroom Activities?

With regard to classroom projects, faculty instructors must be fully familiar with each student's project(s). A student investigator's Faculty Advisor or instructor is ultimately responsible for all aspects of the research a student conducts.

Each faculty and department has the responsibility for: (1) assessing whether student projects/classroom activities involving human participants meet eligibility for review or exclusion from IRB review; (2) overseeing these activities; and (3) assuring that ethical principles are adhered to in the conduct of those activities. Both student investigators and the faculty advisors of undergraduate and graduate students must be certified to conduct research with human subjects. Human Subjects Research ethics training at CU-Boulder is accomplished through the CITI training modules. Information on accessing CITI training can be found on our website, here: <http://www.colorado.edu/innovate/irb/getting-started/citi-training>.

A checklist is available below for assessing whether or not classroom projects meet the criteria for exclusion from IRB review. It is also important that instructors who teach research methods courses educate students regarding the existence of Institutional Review Boards and discuss the relevant ethical issues surrounding the use of human subjects in research. The IRB staff is available to conduct presentations on human subjects research in your class. If you would like to schedule an instructional session with the IRB, feel free to contact us.

Is my Thesis/Dissertation/Honors Research Project "Classroom Research"?

No. **Theses, dissertations, and honors research projects involving human subjects** are considered research as defined by 45 CFR 46 (i.e., "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"). Such independent research projects always require review by the IRB.

I don't plan to publish my Thesis/Dissertation/Honors Research Project. Do I still need IRB review?

Yes. Investigations designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. While such research is often disseminated through scholarly publication or presentation of the data, the results do not have to be published or presented to qualify the activity as research. The IRB assumes that all Thesis/Dissertation/Honors Research Projects intend to contribute to "generalizable (scholarly) knowledge". This makes the project research, regardless of publication. If the research also involves human subjects, then IRB review is required.

Footnotes

A) Sensitive Topics – Any interview, survey or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics requires IRB approval:

- Sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct (pedophilia, bestiality, etc.), practices of contraception, abortion and/or pregnancy
- Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained

- Questions regarding mental health (e.g., suicide, depression, obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.)
- Traumatic experiences of an individual, including war or combat experiences of veterans

B) Vulnerable Populations (for the purposes of classroom research) are any subjects that may be in a position vulnerable to coercion or undue influence to participate in research.

This may include: pregnant women, fetuses, children (with the exception of observational studies), prisoners, persons at high risk of incarceration or deportation, or mentally disabled. Projects involving such subjects require IRB review and submission of a protocol for approval prior to beginning the research.

Classroom Research Project Checklist

This document is intended to assist CU-Boulder instructors in assessing whether classroom research projects may be excluded from review and approval by the Institutional Review Board (IRB). All items below must be satisfied for classroom projects to proceed outside of IRB review.

- The research project is to be performed by students enrolled in a graduate or undergraduate course at CU-Boulder as a requirement for completion of the course.
- The overriding and primary purpose the project is as a learning experience in the methods and procedures of research.
- The instructor is fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.
- There is no intent on the part of the instructor or student to produce generalizable knowledge or to disseminate the findings beyond presentation to instructors or peers in a CU-Boulder educational setting.
- The project involves **minimal risk** to subjects.
- The project does not involve **sensitive topics** or **confidential information** that could place a participant at risk if disclosed.
- The project does not involve persons from **vulnerable populations** as participants.
- The project involves the **voluntary participation** of individuals without any coercion or pressure being placed upon them. The instructor/students have considered whether a consent document should be provided to participants.