

Mt. SAC IRB
Research Activities Conducted as Part of a Course Requirement

The Mt. SAC IRB is charged with protecting the rights and welfare of human research subjects who participate in research projects taking place within the District and/or sponsored by the District. Federal regulations stipulate the type of research that must be regulated by the IRB. Specifically, research is defined to mean “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [56 CFR 46.102]

It is expected that the results of research activities conducted as part of a class or club are not meant to contribute to generalizable knowledge on the research topic. It is recommended that if research conducted as part of a class or club is to be presented at a conference, the following statement may appear somewhere in the presentation:

"This research was conducted as a part of a class or club and is not meant to generalize to the greater body of knowledge on this topic."

While research projects undertaken as part of a course requirement to learn about research methods do not meet the federal definition of research, it is nevertheless the institution's responsibility to ensure that human subjects are protected. Such responsibility is extended to courses involving research using human subjects. Human subject refers to “a living individual (or live specimen) about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.” (**insert citation**). Instructors will monitor the research activities of their students to ensure the protection of research subjects as well as educate students about proper and ethical research methods. The following guidelines must be observed when conducting research activities as part of a course requirement:

1. Research projects assigned in courses containing research on human subjects as part of the syllabus or course requirements must stay within the scope of exempt research, as defined by federal regulation. [56 CFR 46.101(b)] Please refer to the back of this page.
2. Results may be presented to audiences, such as classmates, who understand that the research did not generate generalizable knowledge. However, results from such research projects may only be disseminated, shared at conferences, or published in journals if prior IRB approval has been granted for the research activities conducted as part of the course requirement.
3. To ensure instructors are aware of the most updated federal policies regarding the protection of human research subjects and that such information is shared with their students, instructors requiring research activities as part of their courses are recommended to take the Mt. SAC research ethics courses offered by the Collaborative Institutional Training Initiative (CITI). Certification is achieved by completing the online modules offered free of charge to Mt. SAC employees through the CITI website.

4. Avoid targeting vulnerable populations as human research subjects. Per federal regulations, vulnerable populations include: children (ages 0-17), prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. [45 CFR 46.111(a)(3)]
5. Take appropriate steps to minimize discomfort when researching sensitive topics (e.g., suicide, violence, depression, etc.) that may have intended or unintended negative consequences to human research subjects. If sensitive topics will be examined, care must be taken to inform the subject in advance of possible consequences and obtain consent as well as debrief the subject and provide appropriate resources and/or referrals.
6. Limit and closely supervise any potential data collection outside of campus. Some sites will require IRB approval before allowing anyone access for data collection purposes.

If a faculty member would like to go beyond the research restrictions outlined above, then s/he should consult with the IRB prior to launching the research course.

56 CFR 46.101(b)

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph [\(b\)\(2\)](#) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

56 CFR 46.101(a)

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

	IRB Review	Description of Process in IRB Policies
Cal Poly Pomona	Depends	<u>Research methods courses</u> Students conducting research to learn about the scientific methods as required by a course does not intend to publish or disseminate their results do not meet the federal definition of research and do not need to go through IRB review. The incorporation of CITI training into the classroom work, nevertheless, is highly recommended as ethical review of research is an important aspect of education in research methods. <u>Courses requiring research</u> IRB approval is required but the research must fall within the exempt or expedited review categories of minimal risk. 1. If all students conduct the same research project, the instructor completes an IRB application for the course, includes the syllabus as an attachment. 2. If students select projects from a list, the instructor submits IRB application and addresses each of the topics. 3. If students develop their own projects, each student (or group of students) must submit a brief form (along with the instructor's "umbrella application") addressing all relevant human subjects protection issues for their respective projects.
Cal State Fullerton	Unlikely	A student's project cannot fall under exempt status if the results will be published or if it involves of a topic of potentially sensitive nature or includes participation from a protected vulnerable population.
Claremont Graduate University	No	Classroom-based research projects that will not be published do not need to go through the IRB process. Courses that include a research component or that teach research methods are expected to have a section on research ethics prior to the research activities taking place. Sometimes data from a course research project become part of a dissertation, a paper submitted to a conference or a journal. <i>At the time that this shift from classroom project to research occurs, the use of the data has changed and the research is obligated to subject the research activity to IRB review.</i>
Pomona College	No	IRB approval is not required for projects using human subjects that fall under the auspices of a course. Instructor is assumed to serve as an extension of the IRB and will prevent students from conducting research that would be deemed unethical.
UCLA	Unlikely	Classroom projects that are exclusively intended for instructional purposes and are not intended to contribute to general knowledge or literature in the field need NOT undergo review. When such projects are intended to contribute to generalizable knowledge, they are required to undergo IRB review and approval, prior to the initiation of any research activities, including recruitment of or contact with subjects.
University of LaVerne	Unlikely	Research activities within the context of a course, should comply with the federal guidelines under the supervision of the instructor. The instructor is responsible for reviewing and monitoring student research activities that do not require IRB review and approval. Instructor will forward research studies to the IRB for review as deemed necessary.