

California State University, Long Beach
Institutional Review Board (IRB)
Guidance on Student /Program Projects

I. The Purpose

This guidance is to clarify whether, which, when and how CSULB student projects should be submitted to CSULB IRB to review and approve.

II. Federal IRB Regulations & CSULB IRB Policy Requirements

1. According to federal regulations on the protection of human subjects and CSULB university policies, all student projects that meet the definition of “Human Subjects Research (HSR, as specified below)” must obtain approval or certification of exemption upon CSULB IRB review. The IRB review/approval should take place during the proposal stage prior to the initiation of any HSR
 - individual, and uses, studies, or analyzes the information of biospecimens; or
 - 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
2. IRB is not allowed to retrospectively approve an HSR project, i.e., after it has been conducted.
3. Conducting an HSR project prior to obtaining IRB approval is a violation, which may result in severe consequences.

III. Student Projects That DO NOT Need IRB Submission/Review

In general, projects such as class assignments, capstone projects, etc. assigned to students designed to teach them the skills and practice methods may have a research component. Such projects

course

- C. Conducted in fulfillment of class assignments involving interactions with individuals among or other than the members of the class
- D. Conducte

is in collaboration with an external party or conducted at an off-campus site.

IV. Student Projects That Do Require IRB Submission/Review

Student projects that meet the federal regulatory definition of HSR as specified in Section II.1 do need IRB submission/review/approval.

1. The following student projects DO require IRB review:
 - A. Student projects in the form of directed or independent research, such as honors projects, theses, and dissertations are generally research intended to contribute to generalizable knowledge. Therefore, when they involve human subjects, these projects require IRB review, as with any HSR.
 - B. The student and/or instructor plans to disseminate the data outside of CSULB.
 - C. The student project involves vulnerable populations, sensitive information, or more than minimal risk to the subjects.
2. Examples of student projects that DO require IRB review include, but are not limited to:
 - A. Recruiting vulnerable subject populations, including children/minors, prisoners, pregnant women, mentally or physically challenged individuals, individuals with limited capacity to provide consent
 - B. Intervention/interaction with human subjects causing more than minimal bio-physical risks
 - C. Involving identifiable personal private sensitive information:
 - 1) An individual's psychological well-being or mental health
 - 2) Sexual attitudes, preferences or practices
 - 3) Alcohol or drugs
 - 4) Illegal behavior
 - D. Involving information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employment or reputation
 - E. Involving information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination or stigmatization
3. If the student and/or instructor is uncertain whether or not a student project with human subjects will produce findings worthy of publication or dissemination outside of the immediate classroom environment, that student should submit the project for IRB review. Such projects cannot be initiated prior to IRB approval.

letterhead with signature to:

- 1) certify that the student investigator is knowledgeable about the regulations and policies governing HSR and has sufficient training and experience to conduct the HSR in accord with the IRB protocol,
- 2) agree to meet with the student on a regular basis to monitor the study progress,
- 3) agree to be available, personally, to supervise the student in solving problems should they arise during the course of the project,
- 4) assure that the student will promptly report significant or untoward adverse effects according to applicable policies, and
- 5) arrange for an alternate instructor/faculty adviser to assume responsibility during periods of absence (e.g., sabbatical leave or vacation), and advise the IRB Office by letter of such arrangements.

B. The student and his/her faculty advisor should work as a team to closely follow CSULB IRB submission requirements and instructions posted on the [CSULB IRB website](#), in order to take full responsibility, which includes and is not limited to the following:

- 1) For IRB communication purpose, a student is listed as PI. The student PI has a significant, even primary, research responsibility for a protocol submitted to the IRB. But the course instructor/faculty advisor must be identified, and as supervisor, holds ultimate responsibility for ensuring that the project complies with all regulatory requirements.
- 2) All individuals engaged in research with human subjects must complete mandatory CITI Online training prior to being added to the IRB protocol.
- 3) The faculty advisor/class instructor

- E. IRB Protocols should be submitted well in advance in order to promptly secure approval and to avoid the delay of the HSR projects. Please refer to the [CSULB IRB website](#) for IRB full board meeting dates and submission deadlines.
- F. For HSR projects to be conducted outside of the U.S.A., the PI should refer to CSULB IRB Guidance on International Research, regarding extra preparation time, requirements including Export Control regulations, etc.

V. Class/Program Specific HSR Umbrella Protocols that Do need IRB Review

The purpose/rationale for implementing the Class/Program Specific HSR Umbrella Protocols is to provide the class/program instructors with a useful and convenient tool to meet the IRB regulations while avoiding the burden of requesting each student enrolled in that particular class/program to submit a separate protocol, thus minimizing the time/effort to all the

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VII. References:

1. e-CFR 45 CFR PART 46—PROTECTION OF HUMAN SUBJECTS
2. HHS OHRP “Guidance on Engagement of Institutions in Human Subjects Research”
3. PRIM&R SBER Network Message Board: “Student PIs,” “Research determination for class projects,” “Undergraduate Theses needs IRB Review”
4. UCLA IRB: “Guidance and Procedure: Research Conducted by UCLA Students”
5. USC IRB: “Student Researchers, Student Handbook: Making Sense of Human Subjects Research 2013”
6. Rutgers University IRB: “Research Roles and Requirements”
7. Rutgers University IRB: “Course Related Student Research Assignments”
8. University of Chicago IRB Newsletter: “The Student Issue: Determine whether your research requires IRB Review”
9. University of new Mexico IRB: “Do research projects conducted by UNM students need IRB approval?”
10. Saybrook University IRB: “Do I need an IRB review for my class assignment/Checklist”
11. Collaborative Institutional Training Initiative (CITI) training program
12. UCI IRB: “Undergraduate Researchers”