

**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 activities, including contact or recruitment of subjects. This requirement applies to both funded and non-funded HSR projects.
  - A. Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
    - a) **Human Subject:** a living individual about whom an investigator conducting research:
      - 1) Obtains information or biospecimens through intervention or interaction with the 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 are exclusively intended for instructional purposes and are not intended to develop or contribute to general knowledge or literature in the field or to the public. Therefore, they do not meet the definition of HSR as specified in Section II.1; hence, they do not fall under the jurisdiction of the IRB.

1. For the purposes of this guidance, student projects include the following activities:
  - A. Designed to teach student skills and provide the opportunity to practice methods such as observations, interviews, survey techniques, data analysis, etc.
  - B. Designed to teach research methods through student interaction with individuals or data about individuals or designed to help students understand concepts covered by the

course

- C. Conducted in fulfillment of class assignments involving interactions with individuals among or other than the members of the class
  - D. Conducted during or outside of class, with students enrolled in an official course (for credit or not for credit)
  - E. Not intended to create new knowledge or to lead to dissertation or Master's thesis, a presentation at a professional conference, or a publication in a scholarly journal
2. Student projects specified in Section III DO NOT require IRB submission/review, if they also meet ALL of the following criteria:
- A. The primary purpose is a learning experience in the methods and procedures of research; AND
  - B. All students will use the types of instruments or methods (surveys, questionnaires, interview guides) that are typically used in that particular discipline, to collect the data and/or consent procedures); AND
  - C. There is no greater than minimal risk (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.); AND
  - D. The project does not include sensitive/risky topics or vulnerable populations, such as children or prisoners; AND
  - E. The data are 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, or the recorded data will not identify the subjects through their behavior); AND
  - F. The research takes place in a safe place mutually agreed between the student researcher and the participants; AND
  - G. The data are not to be used beyond the classroom environment (i.e., the data are only for instructional purposes, which can include a course paper or oral class presentation, only disseminated within CSULB campus/community).
3. Even the student projects specified in Section III do not need to go through IRB submission/review process, the class instructors/faculty advisors are strongly recommended to provide adequate training to their students in order for them to be qualified to conduct these projects in an ethical and appropriate manner as per best practices. The training includes:
- A. How to obtain informed consent, how to protect identifiable personal private information, and how to mitigate potential biophysical, psychological, social and/or economical risks, etc.
  - B. How to obtain an appropriate permission letter from an appropriate authority, if research

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.
4. The responsibilities of the student PI and the course instructor/faculty advisor in student HSR projects.
  - A. The course instructor/faculty adviser must provide a copy of supporting letter, in official

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 proofreads, edits and approves all relevant documents.
- 4) All relevant supporting documents are appropriately labelled and attached in the IRBNet submission.
- 5) There should be prompt response to revisions requested by the IRB.
- 6) If any changes are planned to an approved protocol, an amendment to an approved protocol must be submitted prior to initiating the planned changes.
- 7) There should be a prompt report to the IRB of any adverse events, and the corrective actions taken.
- 8) If the original student needs to leave the protocol (such as graduation, etc.), the student PI and the faculty advisor must work together to ensure:
  - i. that the protocol is either closed (i.e., IRB protocol closure as part of the degree audit process), or,
  - ii. that the protocol is promptly transferred to a new PI (either the faculty advisor or a new student who completes the CITI Online training first) prior to the original student PI's departure, and
  - iii. that there is a clear plan on how to retain the data.

C. If the PI plans to conduct research in a non-public off-site (e.g., non-CSULB facility - elementary school, day care center, community center, etc.), at a minimum the PI will need to obtain written permission from an authority of the site (e.g., Principal, Director, etc.) before IRB approval may be granted.

D. For exempt HSR projects, research with minors/children (under 18 years) is an exception. IRB review and approval is required for research involving children.

- 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 stakeholders. In other words, when applicable/interested, only the class/program instructor is required to submit an HSR Umbrella Protocol to cover the HSR projects and list the names of students who have completed CITI training to conduct their specific HSR projects which should meet the following requirements. By doing this, if any particular student's project in the particular class/program gets exciting result, that data can be distributed outside of CSULB since it's covered under the Class Specific HSR Umbrella Protocol.

A Class/Program Specific HSR Project should meet the two key requirements: (1) to be conducted by more than one student but with a similar setting, instruments, informed consent forms, subject populations and methodology, and (2) not involve vulnerable populations, sensitive information/topics, or more than minimal risk to the subjects. If so, the class/program instructor can serve as the PI and submit their own Class/Program Specific Umbrella Protocol to obtain IRB approval.

1. When submitting the umbrella protocol, the class/program instructor should complete a simplified IRB Application form named "Class/Program Specific Umbrella Protocol for Administrative Review," provide sufficient details to clearly identify the learning objective/outcome of the project, the inclusion/exclusion criteria of human subjects, the methods to be used, minimal risks and method of risk mitigations, and data collection and storage. A copy of class syllabus/program description and all necessary supporting documents should be attached to the application.
2. If a change to the above-specified aspects of the study design need to be made, the class/program instructor should submit an amendment to request for protocol modifications.
3. The class/program instructor should make sure that the students complete mandatory CITI Online training first, and include all students as research personnel in the class specific umbrella protocol. Each time when the student turnover occurs, the class/program instructor should submit an amendment to request for personnel change.

## **VI. Contact Information**

If there are any special cases, questions or concerns, students and their course instructors/faculty advisors are strongly encouraged to consult with CSULB IRB Office well in advance, so that issues/concerns can be resolved to avoid the delay of their projects. Email:

[IRB@csulb.edu](mailto:IRB@csulb.edu), Phone: (562) 985-2472. Office Location: FO5, Room #124.

## 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”](#)