

Policy Number: 40

Title: UCI Students and Employees

Date of Last Revision: 08/10/05, 08/20/10, 04/06/18

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review, approve, and provide guidance on the special ethical considerations when UCI students and employees are involved in human subjects research.

- I. **IRB Review and Approval of Research Involving UCI Students or Employees**
 - A. UCI students and/or employees that are asked to volunteer as participants in research are considered a vulnerable subject population because they may feel some pressure to participate, especially if the requesting Investigator is their supervisor or instructor, or someone who might be in a position to influence their future. Students and employees may volunteer to participate out of a belief that doing so will place them in good favor with the Investigator (e.g., participating will result in receiving better grades, recommendations, employment, and the like), or that failure to participate will negatively affect their relationship with the Investigator.
 - B. To protect against even the appearance of coercion or undue influence, Investigators wishing to include UCI Students or Employees must request IRB approval to include this subject population.
 - C. The IRB carefully evaluates the potential for undue influence or coercion when reviewing protocols that include this subject population, and ensures that the protocol includes additional safeguards for voluntary participation in research.
- II. **The Investigator must provide a recruitment plan that includes:**
 - A. The steps that will be taken by the Investigator to avoid even the appearance of pressuring or coercing students and subordinates into enrollment or continued participation in research; and
 - B. The safeguards that will be in place to prevent compromised objectivity and/or confidentiality.
- III. In general, unless approved by the IRB, Investigators may not actively recruit participants from within their own department or classroom. However, this does not preclude members of the Investigator's department or class from freely volunteering to participate. For example, anyone is free to respond to general recruitment advertisements posted around campus or through the Social Sciences Human Subjects Pool.
- IV. The Investigator must assure that any results, performance, or any confidential data will not be given to whoever is evaluating the student or employee.
- V. **UCI Students**
 - A. It is unacceptable to require participation in research for course credit. However, instructors who wish to involve students in simulations of human experimentation and course-assigned data collection for educational purposes only (as opposed to research purposes) may require such participation as part of the class requirements.
 1. UCI students may earn extra course credit through the Social Sciences Human

Subjects Pool if the course instructor includes the extra credit option in the course syllabus.

2. When students participate in research studies for class credit, they must be provided alternative methods of equal or less time and effort for earning that credit.
 3. The IRB may require the investigator to include the available alternatives to participation in the informed consent document.
- B. Investigators interested in accessing student records for research purposes must review the UCI Office of the Registrar policy on Confidentiality of Students Records. The disclosure of information from student records is governed in large measure by the Federal Family Educational Rights and Privacy Act of 1974, by the State of California Education Code, and by University policy and procedures implementing these laws. Generally, documentation of informed consent is required to access private student information.

References:

21 CFR 56.111(b)

45 CFR 46.111(b)

OHRP IRB Guidebook, Chapter 6, Special Classes of Subjects, "Students, Employees, and Normal Volunteers."

Procedure Number: 40.A

Title: Procedure for Review of Research Involving the UCI Students and/or Employees

Procedure:

This procedure provides guidance on the special ethical considerations of students and employees participating in human subjects research under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

I. Lead Researcher (LR) Responsibilities

- A. The LR will submit the IRB Application and Protocol Narrative for any new study in which UCI students or employees will be a target population for research activities.
- B. The research plan should address the following considerations:
 - 1. A rationale as to why is it necessary to include this population;
 - 2. A description of the recruitment plan including how undue influence or coercion and compromised objectivity will be minimized; and
 - 3. A description of the methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered.
- C. The Investigator must provide an informed consent document to the IRB for review containing the appropriate amount of information for the participant to make an informed decision. If, in the opinion of the Investigator, a complete informed consent document is not appropriate, a waiver or alteration of informed consent (Appendix O or P) should be requested including a rationale for the waiver/alteration.
- D. Once approved, the Investigator may proceed with consent of the participant as outlined in IRB Policy 30, unless a waiver has been granted.

II. IRB Committee Responsibilities

- A. The IRB Committee must review the proposed research taking into consideration all applicable UCI policies and procedures, as well as the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the participant. In addition, the IRB must be sure that additional safeguards are in place to protect the rights and welfare of these participants.
- B. The methods in which the full IRB Committee approves a new study submission will be followed. In addition to determining whether the study meets criteria 45 CFR 46.111 for approval, the Primary and Secondary Reviewers must also complete the "IRB Reviewer Checklist" to assure that adequate provisions and documentation of such provisions have been made for this population.
- C. The Committee may not review or make a determination regarding studies involving the UCI students and employees, as a target population, unless it has sufficient expertise in the ethical, clinical, and psychosocial issues impacting this population. Therefore, a Committee member who is knowledgeable about and experienced in working with these subjects must be in attendance at the convened meeting or an expert consultant who has this knowledge must be consulted by the IRB.

III. IRB Analyst or Higher Responsibilities

- A. The Analyst will verify that the IRB Application is completed as part of the initial study documents.
- B. The Analyst will conduct a pre-review and take into consideration the subject population in the proposed research when pre-reviewing the IRB Application, protocol narrative and informed consent documents.

- C. E-mails recommending pre-review changes to the protocol or informed consent documents are to be sent to the LR by the Analyst.
- D. Once the pre-review revisions are received from the LR, the Administrator will forward the revised documents to the assigned Reviewers.