



**University of La Verne Institutional Review Board Policy and Procedure
on Instructor Protocol for Reviewing Undergraduate Student Research
Projects/Course-Based Projects/Graduate Capstones
Approved November 10, 2017, Amended November 14, 2017, November
6, 2018**

Website for Instructors of Course-Based Projects

<https://laverne.edu/irb/mentorsadvisorschairssupervising-faculty/>

Current La Verne IRB Policies and Procedures

Activities in the context of specific courses, including undergraduate senior projects, graduate capstones, and classroom-wide projects should comply with the federal guidelines under the supervision of the course instructor. For research activities that do not require La Verne IRB review and approval, the course instructor carries the responsibility to review and monitor the student(s) research for the protection of human participants and should adhere to all university and La Verne IRB policies when conducting research in a responsible and ethical manner (website for La Verne IRB policies: <https://laverne.edu/irb/policies-and-procedures/>).

All protocols that do not require La Verne IRB review are still required to be submitted to the La Verne IRB for archival purposes (see Procedure for Instructor Approval of Student Protocols, below). Student research, along with all other research on campus, is subject to university policies regarding misconduct, which can include not applying for La Verne IRB approval when necessary.

Note: if you are having students complete La Verne IRB forms as a classroom demonstration, nothing needs to be submitted to the La Verne IRB.

A Course Instructor Must Submit Student Protocols to the La Verne IRB for A Review By the IRB If:

they include empirical research with human participants and if the results are intended to be **published or presented** in professional/academic venues (and/or contribute to generalizable knowledge).

Procedure and Timeline for La Verne IRB Review of Student Projects

The student will be listed as the PI on the protocol and the course instructor will be listed as the

mentor. Instructors are responsible for guiding the student through the process and ensuring the application and revisions are well-prepared and meet the expectations of La Verne IRB review. Further, the La Verne IRB requires instructors to be on all communication between the student and the La Verne IRB, and the instructor shall attempt to answer all questions before they are posed to the La Verne IRB.

The instructor and student should be aware of the time needed to gain approval for their project reviewed through the La Verne IRB. **Student applications should be submitted in the first month of the semester.** Depending on the type of review, and the preparedness of the protocol, the application can take a great deal of time to be approved by the La Verne IRB. **Exempt reviews are typically fast as they utilize a streamlined application.** Standard (full board) reviews are only conducted on the second Friday of the month and may require revisions to be re-reviewed by the board at the meeting after the revisions are received (please review the description of the review process as it contains details of when to submit prior to the La Verne IRB meeting: <https://laverne.edu/irb/expectations-of-ulv-irb-review-timeline/>). The La Verne IRB will make every attempt to review and process student applications as fast as possible, **but reviews can take multiple months to gain approval and may not be approved within a single semester.**

Instructor Guidelines for Leading Student Research Protocols (Adapted from the University of Michigan)

- 1) Review student's plans for class, individual, or group projects, and suggest design improvements and ways to protect confidentiality and/or anonymity.
- 2) Require for the course that the student(s) complete CITI training, for the protection of human subjects in research. The **only accepted trainings** are the Social/Behavioral Basics/Refresher and Biomedical Basics/Refresher. Student trainings and Responsible Conduct of Research trainings **are not accepted.** Also, in some instances additional safety precautions and/or necessary certifications should be considered and provided to the La Verne IRB in the **Mentor Approved Application** (biosafety, laboratory safety, OSHA, etc.). **If working with vulnerable populations or sensitive data, the faculty instructor should be a specialist in this area and have knowledge of proper research and safeguard protocols.**
- 3) Explain the components of informed consent/assent and information sheets. The templates on the La Verne IRB website (<https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/>) are required to be used. The required components defined by the policy on informed consent (<https://laverne.edu/irb/wp-content/uploads/sites/28/2018/08/Informed-Consent-1.pdf>) must be included.
- 4) Explain the difference between anonymity and confidentiality and the necessity of being consistent throughout the study documentation, as the two words are not interchangeable. **Anonymous** means there is no identifiable information in the data that can be traced back to a specific individual, while **Confidential** indicates identifiers are present in the data,

but the researcher will not be sharing this information in a manner that can be traced back to a specific individual, thus protecting the participant.

- 5) Ensure extra protections for studies when students are considering researching participants who are part of vulnerable populations: these are studies that include vulnerable individuals identified in Subparts B-D of 45 CFR 46, which include pregnant women and fetuses, prisoners, and minors (under the age of 18). **Prisoners cannot be studied for student projects as they cannot be approved by the La Verne IRB and must be approved by a national entity.** Further, situational vulnerability must be considered (e.g., a non-vulnerable white male gets rushed to the ER because of a stroke. While in his hospital bed, his medical doctor offers for him to be part of an experimental study for stroke patients).

Examples of vulnerable populations include, but are not limited to, adults who are under legal guardianship, persons with intellectual or developmental disabilities, frail elderly, and low income when the study has a high incentive (The University of Virginia lists eight categories of vulnerability; refer to their website for specific examples (http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln_eight.html)).

- **In a similar vein to UC Berkeley, the La Verne IRB strongly recommends that an undergraduate student who wants to study a vulnerable population instead communicates with spokespeople, representatives of the group, expert informants, and/or professionals who work with the community. Secondary data on the populations is also highly recommended.**
- **Members of the vulnerable group should not be asked sensitive questions where if the information were made public (i.e., through data breach) they would be at risk.**

If working with vulnerable populations or sensitive data, the faculty instructor should be a specialist in this area and have knowledge of proper research and safeguard protocols.

- 6) Extreme caution and extra precautions should be exercised if students propose studies where participants are to be asked about extremely sensitive behavior (e.g. depression, suicide, illegal behavior, drug or alcohol use, sexual activity or abuse, traumatic experiences, etc.). **If working with vulnerable populations or sensitive data, the faculty instructor should be a specialist in this area and have knowledge of proper research and safeguard protocols.**
- 7) Explain ways in which students should be attentive to potential language and miscommunication problems in conducting research. Also, discuss the equitable selection of participants.
- 8) Teach students the necessity in using clear and concise language with specific details and to double-check the meaning to prevent legal consequences.

- 9) Consider **ALL** risks involved and ways to safeguard human subjects in the research setting and throughout the entire proposal. State the risks and safeguards in the consent form/information sheet.

Risks and Safeguards:

Informational: If confidential, the identity of participants may be known or participants might be embarrassed if their names are linked to responses. (Typically, this means risk is minimal; for non-sensitive surveys, provide abbreviated informed consent information – purpose of study, student and faculty contact information. For sensitive surveys, provide more detailed informed consent information and switch to an anonymous research design.) Anonymous surveys lower this risk. **Safeguards:** if confidential, tell the participants in the consent form/information sheet their data will be protected securely and describe how (e.g., Paper forms: locked in a stationary cabinet in researcher’s non-University of La Verne Office).

Psychological: sensitive or discomfoting questions. **Safeguards:** 1) include contact information for the Counseling Center in the consent/information sheet – required to notify the Counseling Center and receive acknowledgement before beginning research or 3 community counseling referrals, 2) conduct research via email or in a controlled setting (classroom or laboratory with faculty oversight; include debriefing if particularly sensitive), and 3) consider use of previously used survey instruments (with permission) where wording has already been tested.

Physical: potential harm or stress. For example, risks should not exceed what would be part of a typical physical education class or experiential learning exercise. **Safeguards:** Projects examining ingestion must have a supervising registered dietician, other studies that involve physical risk should have specialists who can mitigate those risks, supervising medical doctors, etc.

Social Group: social group risk relates to participants being members of or part of a group and having that relationship impacted by participating or not in the proposed research. For example, if a professor wants to conduct research on his/her students, in this instance students at La Verne may be at risk and should be told in the informed consent/information sheet that by participating or not in the research study, nor the content of their answers, will their relationship with La Verne and the professor be jeopardized in any way (which is a **safeguard**). Another typical scenario for social group status risk is the use of employees in research and participation jeopardizing their employment status.

- 10) If you are qualified, explain ways in which students should be attentive to the posing of sensitive questions, including topics related to sexual activity, victimization, use of alcohol or illegal drugs, or involvement in illegal activity. If you do not specialize in such

an area, the student should change their research emphasis or consult with an instructor with specific expertise in that area to ensure proper communication.

- 11) If the students propose working with residents of the European Economic Area (EEA) for their research project, you will ensure **all** GDPR procedures will be followed and take responsibility for making sure EEA resident inquiries are addressed immediately as per the international research policy (<https://laverne.edu/irb/wp-content/uploads/sites/28/2018/10/La-Verne-IRB-International-Research-GDPR.pdf>), in order to ensure the avoidance of a minimum fine of 2-4% of the gross domestic product of the United States. If students are not proposing to work with EEA residents, they **must** clearly write their study population (e.g., Americans) in their consent forms/information sheets.
- 12) Suggesting, as much as possible, anonymous data collection so data is not linked to individuals. If there is information identifying individuals, suggest ways to keep identifying information separate from responses and the data protection policy from the La Verne IRB is followed (see step 13).
- 13) Requiring the student to collect the minimum demographic and sensitive information possible for their study to be practicable; the fewer data stored, the lower the risk.
- 14) Following storage procedures required by the La Verne IRB: <https://laverne.edu/irb/wp-content/uploads/sites/28/2018/09/La-Verne-IRB-Data-Protection-Policy-Updated-Sept-2018.pdf>
- 15) Verifying the students **are not planning to conduct a raffle**. Raffles require the advanced purchase of tickets, the raffle registered with the State of California at least 60 days prior to the raffle, along with other requirements that student and faculty research projects do not meet. For more information, refer to this website: <https://blink.ucsd.edu/sponsor/advancement/advancement-services/gift-processing/list/raffles.html>
- 16) Evaluating compliance with CA law of opportunity drawings. Students may conduct an **opportunity drawing in increments under \$24.99** (over that amount and tax forms will need to be completed in order to report the funds as income to the IRS). **California law requires that opportunity drawings have "general and indiscriminate distributing of tickets."** For the La Verne IRB, we interpret this to mean the drawing is open to all who want to join and not just people who participate in your study. **Verify the informed consent/information sheet should account for this portion of the law (e.g., not stating the drawing is restricted to participants).**
- 17) Make sure the student obtains all necessary permissions to conduct their research.
- 18) Consider if there any potential problems if the research goes public. If so, the research will need to be adjusted for the students' skill level to avoid issues that could affect the university.

Procedure for Instructor Approval of Student Protocols in IRBManager

If you approve **individual student (graduate or undergraduate) projects** as the instructor, the following steps must be followed:

- 1) the student will complete the Mentor Approved IRB Application in IRBManager (accessible at laverne.my.irbmanager.com) and an informed consent (if applicable), which can be found at: <https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/>.
- 2) The students will revise and update the application and documents until you approve their content.
- 3) The Mentor Approved applications are archived without formal La Verne IRB review as it is assumed the instructor is taking responsibility for the project(s). An example of the Mentor Approved Application, along with step-by-step guides and tutorials for completing the form can be found on our website: <https://laverne.edu/irb/students/>
- 4) The student and instructor will update the La Verne IRB with any significant changes in risk to human participants throughout the course project.