IRB GUIDANCE DOCUMENT: UNDERGRADUATE STUDENT RESEARCH PROJECTS/COURSE-BASED PROJECTS/GRADUATE CAPSTONES
Approved November 10, 2017

Website for Instructors of Course-Based Projects

http://sites.laverne.edu/institutional-review-board/mentorsadvisorssupervising-faculty/

Current La Verne IRB Policies and Procedures (approved September 20, 2012)

Course-Based Projects or Research Activities. 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. The course instructor may choose to forward a research protocol for review by the La Verne IRB as deemed necessary by the instructor.

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.

A course instructor must submit student protocols to the La Verne IRB for a review by the IRB **if**:

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

Procedure for Instructor Approval of Student Protocols

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

1) the student will complete the downloadable Initial La Verne IRB Application (not electronically in IRB Manager) and an informed consent (if applicable), which can be found at: http://sites.laverne.edu/institutional-review-board/irb-forms-and-examples/. Please check for updates on these forms each semester prior to distributing them to the students.
2) The students will revise and update the documents until you approve their content.

3) Once approved, the student will complete and submit a Mentor Approved Application in IRBManager. These forms replace the old Faculty/Advisor Form that was required to be sent to the La Verne IRB for all projects. 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: http://sites.laverne.edu/institutional-review-board/student-applicants/
4) The student or mentors will update the La Verne IRB with any significant changes in risk to human participants throughout the course project.

Alternatively, for projects that extend to all or a large portion of the students in a course, the instructor will complete and submit a Mentor Approved Application in IRBManager. These forms replace the old Faculty/Advisor Form that was required to be sent to the La Verne IRB for all projects. 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).

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.

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. 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 our description of the review process as it contains details of submission time prior to the La Verne IRB meeting: http://sites.laverne.edu/institutional-review-board/submitting-your-irbapplication/). 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 (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.

3. Explain the components of informed consent/assent.

4. Explain the difference between anonymity and confidentiality and the necessity of being consistent throughout the study documentation.

5. For students who 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). Further, situational vulnerability must be considered. 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)):

o 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.
o 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, unless the member is one of the representatives listed in 2(a) above.

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.),

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.

10. 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.

11. Suggesting, whenever 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.

12. Suggesting students not study vulnerable populations, but instead spokespeople,

representatives of the group, expert informants, professionals who work with the community, and/or secondary data. Instruct students about the privacy and security vulnerabilities associated with computers, networked systems, and the internet.

13. Suggest appropriate records management storage and archiving techniques, including the destruction of data and password protection.

Key Questions for an Instructor to Answer When Making Approval Determinations on Student Applications

• *What are the risks associated with the research?*

Informational: 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.) Anonymous surveys usually lower this risk.

Psychological: sensitive or discomforting questions. Options: 1) include contact information for the Counseling Center –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. Projects examining ingestion must have a supervising registered dietician.

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 that by participating or not in the research study, their relationship with La Verne and the professor will not be jeopardized in any way. Further, their decision to participate or not will not be linked to their student status with La Verne. Another typical scenario for social group status risk is the use of employees in research and participation jeopardizing their employment status.

• Is the research being conducted in a controlled environment?

Is the research non-sensitive, so students wouldn't be embarrassed if taking convenience samples (such as soliciting in library, classroom, campus center or other public places)?

• Has a student researcher had appropriate training or instruction on how to conduct research? Will they be supervised throughout the research process?

Online training regarding the protection of human subject's in research is required and available at CITI (see the IRB website for more information); it should be completed by student researchers and research assistants, with certificates forwarded to the La Verne IRB via the **Mentor Approved Application** in IRBManager. 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, OHSA, etc…).

• Is permission needed from an outside organization or campus department?

Make sure the student obtains all necessary permissions to conduct their research.

• Does the project pass the 60 Minutes (journalism TV show) test?

Are there any potential problems if the research goes public?