University of La Verne Institutional Review Board (IRB)  
For The Protection of Human Participants in Research  
Policies and Procedures  
Revised and Approved: September 20, 2012

I. Preamble

The University of La Verne believes in the value of research involving human participants, and accepts an ethical responsibility for safeguarding their rights and welfare with due consideration to ethnic and cultural issues (Code of Federal Regulations, Title 45, Part 46, Department of Health and Human Services, Protection of Human Subjects, Revised, June 18, 1991).

II. Policy

A. Definition:
According to the federal rules Title 45 (Code of Federal Regulations, Part 46, 46.102) research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

Human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

B. Application of Policy:
This policy applies to all faculty, all staff, all administrators, and all students who are conducting or supervising research involving human participants, regardless of whether the participants are members of the University of La Verne community. Heads of units such as department or program chairs, and deans are responsible to bring this policy to the attention of their faculty, staff and students.

C. Responsibility:
Final responsibility for the protection of human participants and adherence to ethical standards rests with the University. However, primary responsibility for any one project rests with the research investigator/researcher and supervising faculty involved in these activities.

Note 1: Projects related to outcomes assessment and program review at the University of La Verne should have a designated principal investigator who carries the responsibility for the protection of human participants, and seeks IRB approval as appropriate.
Note 2: Review and approval of research conducted on campus by investigators not associated with ULV. The review process for outside investigators wishing to recruit participants and/or research on ULV campuses requires the following:

1. If data are collected on campus at a specific multi use site or in multi use classrooms, the researcher must obtain written permission to collect data from an administrative professional who has authority over the area (administrative approval does not automatically render classroom instructor approval-see # 2 below).

2. If classroom time is required for participant recruitment or conduct of the researcher, each classroom instructor must give at least verbal permission. Every effort must be made to limit impact on classroom instructor.

3. The outside researcher is encouraged to include, as part of the research team, a research contact person who is either a full time faculty member or holds an administrative/professional position. The outside researcher and any ULV members of the research team must be certified in the IRB policy and procedures.

4. If the outside researcher does not have a University of La Verne faculty member or administrator/professional as part of the research team, the application shall be submitted directly to the IRB chair for review. The outside researcher shall include a copy of the IRB application and approval from the researcher’s university. Approval may be granted conditional, pending receipt of IRB approval. The IRB Chair will be the primary reviewer for outside applications that request permission for the recruitment of participants through flyers or publically available email addresses for faculty, staff, and/or administrators (Exempt and Expedited reviews).

D. References:
For guidance concerning ethical standards the following references should be consulted, copies of which are available in the office of the Provost and Vice President for Academic Affairs, as well as in the offices of the academic College and School Deans.


3. American Psychological Association Ethics Code (1992), American Psychologist, 47, 1597-1611 (Section 6.0). (Revision under review.)


5. Whenever appropriate, ethical codes of related professional associations and academic disciplines should be consulted.
III. Implementation

A. Responsibility:
The implementation of the policies for the protection of human participants in research is shared by the Colleges and the Office of the Provost.

B. Documentation:
Each empirical master's thesis or doctoral dissertation involving human participants as sources of information must document in an appendix that the research project has been specifically reviewed for compliance with ethical standards and has been approved by the University IRB prior to the start of data collection. A copy of the Approval Action Form or IRB Approval Letter would be appropriate documentation (see Appendix B).

Note 1: All doctoral dissertation research projects shall be submitted for review by the IRB prior to the start of data collection (at proposal approval stage), regardless of review category. The IRB will determine whether a project is exempt. Graduate Academic Services requires that all submitted dissertations include documentation of IRB approval.

C. Course Based Projects or Research Activities:
Activities in the context of specific courses, including senior projects, should comply with the federal guidelines under the supervision of the course instructor. For research activities that do not require IRB review and approval, the course instructor carries the responsibility to review and monitor the student research for the protection of human participants. The course instructor may choose to forward a research protocol for review by the Area IRB as deemed necessary by the instructor.

D. Senior Projects
Senior projects that include empirical research with human participants must be reviewed by the IRB only if the results are intended to be published or presented in professional/academic venues (contribute to generalizable knowledge). Faculty advisors assume the responsibility for protection of human participants for senior projects, and may choose to have the senior project reviewed by the IRB at their discretion.

Note 1: Written guidelines, including frequently asked questions, are available from the IRB related to course and senior projects.

E. Review Process
The review process shall determine:
1. Potential risks to the dignity, rights and welfare of the participants.
2. That the proposed safeguards against the risks are adequate.
3. That the procedures to obtain informed consent are appropriate and the forms used are complete, clear and non-coercive.
4. That, for research which involves more than minimal risks, the benefits to the participants outweigh those risks.

Note: The review process does not evaluate the design of the study as such, except as it may impact the welfare of the participants.
F. Protocol Categories:
There are three categories for review by the University IRB under which researchers must choose to submit their application. These categories reflect the nature and the level of potential risk to participants.

1. "Standard Review" Category
Research is required to be submitted under Standard Review category if one or more of the following conditions is involved:
   a. More than minimal legal, physical, or psychological risk, or
   b. Children under the age of 18, and adults who are under legal guardianship or otherwise require special concern (example, persons with intellectual or developmental disabilities, frail elderly, prisoners), or
   c. The identity of subjects can be linked to information provided by the subjects, by persons other than the researcher, or by way of the research procedures.

2. "Expedited Review" Category
Research which does not require a Standard Review, but which involves minimal risk, should be submitted under the Expedited Review category. Examples of activities appropriate for Expedited Review are the following:
   a. Surveys, interviews, questionnaires, observations, and content analysis in which the participants' identity and responses are confidential or anonymous.
   b. Recording of data from participants 18 years of age or older using non-invasive procedures routinely employed in clinical practice, and which does not involve invasion of privacy.
   c. Voice recordings made to study speech/language disorder, or data collected from video, digital or image recordings.
   d. Moderate exercise by healthy volunteers.
   e. The study of existing data, documents, records, pathological specimens in which the identities of subjects are kept confidential but in which subjects are not anonymous.
   f. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to participants.

Note: For additional information, please see Appendix F.

3. "Exempt Review" Category
Research that does not require either a Standard Review or an Expedited Review is reviewed by the IRB under the Exempt Review Category. All research involving survey or interview is exempt without exception when the respondents are elected or appointed public officials or candidates for public office. In compliance with 45 CFR 46, Protection of Human Subjects (revised, 46.101, [1]-[6]), Exempt Review is appropriate for research activities in which the only involvement of human participants will be in any of the following:
   a. Established or commonly accepted educational setting, involving normal pedagogical practices such as: (1) Regular and special education instructional strategies; (2) Comparison among instructional techniques, curricula, or
classroom management methods.

b. The use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, unless the research entails any one of the following: (1) Participants could be identified directly or through identifiers linked to them; (2) Disclosure of participants’ responses outside the research could reasonably place them at risk of criminal or civil liability, or damage their financial standing or employability; (3) Sensitive aspects of the participant’s behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol; (4) The human participants are children, or developmentally disabled or mentally ill adults who have legal guardians.

c. Observation, including participant observation of adults, of public behavior in settings where the participants have no reasonable expectation of privacy and their responses cannot be linked to them, unless the subjects are children, or adults who must be given Standard Review (i.e., members of a vulnerable population).

d. Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available and cannot be linked to the participants.

e. Research and demonstration projects conducted by or subject to the approval of administrators and which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies (wholesome foods or without contaminants).

Note: For additional information, please see Appendix E.
Upon review, the IRB may transfer an application from one category to another depending on the nature of the research and risk to human participants.

G. Collaborative Organization Permission:
Written permission is needed from any agency, school, clinic, or other organizational entity whose cooperation is required in obtaining access to participants and conducting research. Such permission must be available during the review process as part of the IRB application, and documented as an appendix to the research report. Conditional approval may be given to an IRB application, with a requirement that permission documentation be provided prior to beginning research. Permission may be documented on letterhead or by verifiable email.

Note 1: The University of La Verne IRB assumes responsibility for primary review of all student research, regardless of the involvement of collaborating organizations as settings or providers of participants.

Note 2: Use of ULV Counseling Center as a referral resource for human research participants.

Research that is of psychological nature or that asks participants to report on sensitive social or personal issues may, at times, provide long term emotional reactions. On the judgment of the investigators, or by recommendation of the IRB, an investigator may offer participants a
referral for counseling services.

The University of La Verne Counseling Services may be offered as a counseling resource under the following conditions:

1. The referral resource may be offered ONLY to research participants who are current students, faculty or staff of The University of La Verne.
2. The investigator must notify the Director of ULV Counseling Center regarding the nature of the research; and,
3. The investigator must submit to the IRB acknowledgment of the notification by the ULV Counseling Center Director.

* The current Director of the ULV Counseling Center is Dr. Richard Rogers, who may be contacted at (909) 593-3511 x 4832, or e-mail at rrogers2@laverne.edu.

H. Informed Consent Process
Informed consent process shall address the following three major ethical concerns:

1. The ability and desire of individuals to decide whether they want to participate in research by providing adequate information about what will be done to or asked of them.
2. The need for participants or their representatives to understand the nature and extent of potential benefits and risks to themselves.
3. The need to give informed consent freely without pressure or inappropriate inducements of any element of force, fraud, deceit, constraint or coercion.

Note: See General Requirements for Informed Consent and Sample Informed Consent Form, Appendices C and D.

I. Institutional Review Board Action:
The IRB when reviewing a protocol will take one of the following actions:

1. Return the application without review; Insufficient detail to adequately assess risks, protections, and benefits;
2. Approve/Certify the application as Exempt from IRB Review;
3. Approve the application as submitted;
4. Approve the application, contingent on minor revisions;
5. Require significant modification of the protocol before approval; Researcher may resubmit with modifications; or
6. Request the investigator discuss problems with the Area IRB Member or University Research Coordinator. The IRB may be required, or choose, to request that an outside expert reviewer join the IRB in the assessment of an application.

IV. Organizational Structure, Membership and Division of Responsibilities in Compliance with the Code of Federal Regulations Title 45, Part 46.107 (1991):

The University IRB

1. Is sufficiently qualified through the experience, expertise, and diversity of its members, including sensitivity to community attitudes, to command respect for its
advice and counsel in safeguarding the rights and welfare of research participants;

2. Does not consist entirely of men or women or entirely of persons in one profession, or of any one ethnic group;

3. Has one member whose primary expertise is in a non-scientific area;

4. Has one member with no formal affiliation with the University;

5. May seek consultants at any time who do not participate by vote.

Thus, the University IRB is composed of seven (7) members in total (quorum is established at four members including designated alternates):

1. The University Director of the IRB;
2. Four Area IRB members (one per college) representing the four academic Units of ULV; the College of Law member is also designated as a non-scientific member.
3. One staff/administrative member
4. One member without university affiliation.

Note: See IRB Organizational Chart attached as Appendix K.

A. Area IRB Membership:
Each of the four academic colleges is represented in the University IRB by one voting Area IRB Member and up to three alternates at all times. The Colleges and Schools are: College of Arts and Sciences, College of Business and Public Management, LaFetra College of Education, and College of Law. Area IRB Members serve on staggered three-year terms, serving the first two years as an Alternate Member, followed by one year as a Full Voting Member.

B. Non-Scientific/Non-Affiliated IRB Membership:
The non-university affiliate member is appointed or re-appointed by the Provost for a term that begins on June 1 and ends on May 31.

C. Selection of Area IRB Members:
The Area IRB Members and Alternates are selected by each College and recommended to the Provost.

D. College Recommendations for Area IRB Members:
Each College may decide how they select the Area IRB Members and Alternates for recommendation to the Provost.

E. University Director of the IRB:
The University IRB is coordinated and convened by the University Director of the IRB who Chairs and is a voting member of the University IRB, and reports to the Provost.

F. Responsibilities:
   1. The Area IRB Members:
      a. Receive all IRB protocol applications from their respective Colleges;
      b. Approve, on behalf of the University IRB, all IRB protocols submitted under the Exempt and Expedited Categories, and forward approval letters/Approval Action Forms with the protocols to the Director of IRB for documentation. (Note: some or all of this responsibility may be assumed by the IRB Chair/Director upon approval of
an Area IRB; federal regulations provide for Exempt and Expedited reviews to be approved by the IRB Chair or delegate.)

c. Protect the confidentiality of all discussions surrounding decisions whether written, electronic or verbal and adhere to protections afforded under Family Educational Rights and Privacy Act (FERPA), as amended.
d. May suggest minor modification to the protocols to facilitate compliance with IRB standards.
e. Forward electronically all IRB protocol applications submitted under the Standard Category to the Director of IRB for review by the University IRB.
f. May shift submitted protocols from one review category to another as deemed appropriate.
g. Meet monthly as members of the University IRB convened by the Director of IRB (or more or less frequently on an as-needed basis).

2. The University Director of the IRB:
   a. Receives and reviews from the Area IRB Members signed Approval Action Forms and the protocols submitted under the Exempt and Expedited Categories for archival documentation and issues Approval Letters. The IRB Director may assume additional responsibilities for Exempt and Expedited reviews if approved by an Area IRB.
   b. Receives from the Area IRB Members an electronic copy of protocols submitted under the Standard Category, and distributes in a timely manner copies to the University IRB members, prior to the meeting of the University IRB.
   c. Protects the confidentiality of all discussions surrounding decisions whether written, electronic or verbal and adheres to protections afforded under Family Educational Rights and Privacy Act (FERPA), as amended.
   d. Informs the applicant in an electronic memo about the decision and provides a copy of the signed Approval Action Form or Approval Letter to the applicant.
   e. Communicates with the applicants concerning the actions of the University IRB related to reviews in the Standard Category.
   f. Maintains an electronic and a hard-copy file of actions taken by the Area IRB Members and the University IRB.
   g. May re-categorize submitted protocols across categories as deemed appropriate.
   h. Prepares an annual report, or such other reports as deemed necessary, of the University IRB activities for the Provost.
   i. Review applications from unaffiliated or outside researchers submitted under the Exempt and Expedited Categories.

G. Training of IRB Members:
All members of the University IRB (including alternates) are:
  1. Expected to be familiar with the policy guidelines of the Office for Human Research Protection of the U.S. Department of Health and Human Services (Link available at the IRB website)
  2. Expected to be familiar with the Ethical Principles of the Belmont Report available at the web site mentioned above or in the IRB Office or on the IRB website.
  3. Expected to take the brief computer based training (CBT) offered by the National Institutes of Health (NIH) for all investigators and persons involved in research (Link
available at the IRB website). CITI training may be substituted for this requirement at such time the University subscribes to this service.

Note 1: Upon completion of the NIH Certification Test, a copy of the Certificate of Completion must be forwarded to the Office of the IRB Director. Certifications must be on file prior to the review of any application to conduct research. Certification must be on file for all faculty advisors who are submitting/co-signing student research projects.

H. Training of Faculty, Staff and Administrators Involved in Research:
All Faculty, Staff, and Administrators who teach, conduct or supervise empirical research involving human participants at the undergraduate or graduate level are:

1. Expected to take the brief computer based training (CBT) offered by the National Institutes of Health (NIH) for all investigators and persons involved in research (Link available at the IRB website). CITI training may be substituted for this requirement at such time the University subscribes to this service.

Note 1: Upon completion of the NIH Certification Test, a copy of the Certificate of Completion must be forwarded to the Office of the IRB Director. Certifications must be on file prior to the review of any application to conduct research. Certification must be on file for all faculty advisors who are submitting/co-signing student research projects.

H. Conflict of Interest:
No IRB Member may participate in the IRB’s initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.

Note 1: An IRB Member may participate in review if serving as a faculty advisor. If a project is part of a faculty research project or grant-funded, the IRB Member must recuse himself/herself.

Note 2: An IRB Member or IRB Chair who is the principal researcher or investigator on a project must recuse himself/herself. For the IRB Chair, the project will be reviewed by the affiliated college Area IRB member. For other IRB members, the project will be reviewed by an alternate (other) member(s) of the college IRB committee.

V. Timelines for Action by IRB
A. Exempt and Expedited Categories:
Protocols submitted under the Exempt and Expedited Categories are reviewed by the individual Area IRB Member representing a college within seven days after the receipt of an electronic copy of a complete application. Each college may adopt its own protocol for having Exempt and Expedited protocols reviewed by a single IRB member and/or as a College IRB Committee that includes the Area IRB Member and alternates. All IRB members will be advised of research proposals which have been approved under the procedure through posting of an activity log on Blackboard and/or by reporting at IRB meetings (46.110).

B. Standard Category:
Protocols submitted under the Standard Category are reviewed by the University IRB at its monthly
meetings, provided an electronic copy of a complete application is received and distributed to IRB members a minimum of one week prior to the meeting date. (Complete application means that an application has been reviewed by the Area IRB prior to distribution; therefore, the application would generally need to be submitted by the applicant earlier in order to allow for adequate review and for any corrections.) Meeting dates are announced for the whole year at the start of each new academic year.

C. Period of Approval:
The IRB will monitor all approved studies on an ongoing basis. The IRB will determine in each individual case how frequently a project will be reviewed based on the degree of risk to human participants involved. Both the research protocols and the adequacy of informed consent must be reviewed at least annually. Reviews may be conducted more frequently as determined by the IRB, and research operations may be observed by the IRB at any time.

Investigators must submit progress reports according to the frequency determined by the IRB. Failure to do so may result in suspension of the project. Report format at a minimum includes number of participants enrolled, notable findings, problems in enrollment or retention of participants, and adverse event reports.

D. Extensions:
Research project approvals can be extended by submission of a progress report and request for extension to the University Research Coordinator. The form for an Application for Extension is available on the IRB website.

Note 1: Review of amendments to approved protocols.
Applications for amendments to previously approved protocols are reviewed following the same principles as new applications. Based on the level of risk to participants, and whether the proposed amendment raises, lowers or does not affect the level of risk, the IRB Chair may choose to:

1. Review the application and provide sole expedited review and approval (for minor amendments that lower or have no impact on the level of risk to participants).
2. Review the application in consultation with the college IRB representative who provided expedited review and approval for the original application (for major amendments that lower, or have no impact on, the level of risk to participants).
3. Forward the application to the college IRB representative for full standard review (for amendments that significantly increase the level of risk to participants or involve adding vulnerable populations to the potential participants).

VI. Sanctions
A. Invalid Data:
Data collected from human participants without IRB approval will be considered invalid and will be discarded. No empirical research involving human participants, conducted by a student of the University of La Verne, will be permitted as part of a Masters or Doctoral thesis without prior approval of the University IRB.

B. Faculty and Staff Consequences:
Investigators who collect data from human participants without IRB approval will receive a letter of
reprimand from the Provost, and a copy of the letter will be placed in their personnel file.

**VII. Adverse Events**
If there is an adverse event during the data collection phase of the study that has presented an unanticipated risk, and may have potential liability for the human participant(s), researcher, or institution, it must be reported as soon as reasonably possible, but no later than seven (7) working days subsequent to the adverse event, to the Office of the URC using the form entitled, Adverse Event Report Form.
Note: See Adverse Event Report Form, on the IRB Website.

**VIII. Retention Schedule**
All applications and records related to this approval process will be maintained by the Office of the Director of IRB for a period of at least three (3) years and records relating to research that has been conducted shall be retained for at least 3 years after completion of the research. Records may be maintained longer if required for grants or by government regulation or law. Institutional Review Board summary records and reports will be maintained by the IRB Director permanently in a medium conducive to such permanent record keeping.

Note: All forms are available at [http://www.laverne.edu/academics/institutional-review-board/forms](http://www.laverne.edu/academics/institutional-review-board/forms) and may be downloaded as Microsoft WORD files.