University of La Verne Institutional Review Board Policy and Procedure on The Protection of Human Participants in Research Approved September 20, 2012, Amended May 12, 2017, May 11, 2018

1. 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).

2. 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*:
The La Verne IRB policies and procedures apply 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 these policies and procedures to the attention of their faculty, staff and students. The policies and procedures are divided into smaller parts, in separate documents, to allow for easy amendment. This document is the introduction to those policies and describes who must apply, the protocol of the review and informed consent process, the IRB structure, sanctions, adverse events, and the retention schedule.

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: 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.

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.

1. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education and Welfare, April 18, 1979.
2. Code of Federal Regulations, Title 45, Part 46, Department of Health and Human Services, Protection of Human Subjects, Revised January 15, 2009, Effective July 14, 2009.
3. American Psychological Association Ethics Code (1992), American Psychologist, 47, 1597-1611 (Section 6.0). (Revision under review.)
4. Council of National Psychological Associations for the Advancement of Ethnic Minority Interests (CNPAAMI) (2000), Guidelines for Research in Ethnic Minority Communities. Washington, D. C.: American Psychological Association.
5. Whenever appropriate, ethical codes of related professional associations and academic disciplines should be consulted.

3. 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 IRB Approval Letter would be appropriate documentation.

> Note: 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 or not human subjects research (NHSR). 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 and Masters Capstones*
Senior projects and Masters capstones 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: An instructor guidance document is available on the IRB website that provides specific policy, procedures, and guidelines for senior thesis projects and Masters capstones: https://laverne.edu/irb/wp-content/uploads/sites/28/2017/01/IRB-GUIDANCE-DOCUMENT.pdf

E. *Student Research Other than Listed Above*
Students engaging in human subjects research while a student at the University of La Verne must have their research reviewed by the La Verne IRB. It is suggested they contact the Director first to ascertain their engaged status.

F. *Faculty/Staff/Administration Research*
All faculty, staff, and administration engaging in human subjects research must have their research reviewed by the La Verne IRB. The IRB will determine whether a project is exempt. Faculty conducting research with investigators who are not affiliated with the University of La Verne are still required to submit an application with the La Verne IRB for review and approval. It is suggested they contact the Director first to ascertain their engaged status.

G. *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.

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.

4. 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 La Verne; the College of Law member is also designated as a non-scientific member.
3. One staff/administrative member
4. One member without university affiliation.

* In colleges that require more than one Lead reviewer, who is the voting member, the vote is shared so that one Lead is designated as the voting member at meetings.

Note : Membership is described in detail in the Member Positions and Duties policy.

5. 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, Staff, and Administration Consequences*:

Investigators who collect data from human participants, or permit their students to do so, 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. For their first infraction, every effort will be made to provide education to the investigators and a chance to correct their behavior prior to a letter being issued. If the investigators correct their behavior, a letter will not be issued.

6. 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 IRB using the form entitled, Adverse Event

Report Form.

7. Retention Schedule – Applicants

The data and informed consents must be destroyed in a manner that protects the identity of the human subjects at 3 years since the conclusion of the study. Faculty, staff, and administration may apply to keep the data for a longer period of time (this must be specified in the IRB application). If the data are approved to be kept more than 3 years, the corresponding informed consents must also be retained. If the data are anonymous and an informed consent was not used to collect the data, informed consents are not required to be retained with the data if approved for retention beyond 3 years.

8. Retention Schedule – IRB

All applications and records related to this approval process will be maintained La Verne IRB Administration 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, templates, policies, and procedures are available for download at:
https://sites.laverne.edu/institutional-review-board/