

University of La Verne Institutional Review Board Policy for Review Turnaround Time and Period of Approval Approved February 10, 2017

Pre-Review by La Verne IRB Administration:

All applications undergo a pre-review by either the La Verne IRB Analyst or La Verne IRB Chair, which will identify missing documentation, incomplete answers, and any other application insufficiencies that will prevent a full review by the La Verne IRB reviewers. La Verne IRB Applications will not be moved on for review by the Area (College) La Verne IRB Members until all deficiencies are corrected.

Exempt Category:

Exempt protocols are reviewed by the La Verne IRB Analyst and the La Verne IRB Chair. Each La Verne IRB administrator has three business days to review the protocol once received. All La Verne IRB members will be advised of exempt research proposals that have received a determination through posting of an activity log on Blackboard and/or by reporting in IRBManager. (46.110).

Expedited Category:

Protocols submitted under the Exempt and Expedited Categories are reviewed by the individual Area La Verne IRB Members, representing a college, within a goal of three business days (seven business days maximum) after the receipt of an electronic copy of a complete application. If a reviewer requires more than that timeframe, they will contact the La Verne IRB Chair to make appropriate arrangements. Both the research protocols and the adequacy of informed consent must be reviewed at least annually. La Verne IRB members will be advised of expedited research proposals which have been approved under the procedure through posting of an activity log on Blackboard and/or by reporting in IRBManager. (46.110).

Standard Category:

Protocols submitted under the Standard Category are reviewed by the University La Verne IRB committee at a designated monthly meeting, provided an electronic copy of a <u>complete</u> application is received and distributed to La Verne IRB members a minimum of one week prior to the meeting date. A <u>complete</u> application means that it has been reviewed by the Area IRB prior to distribution; therefore, the application would generally need to be submitted by the applicant earlier (two weeks prior to meeting date) in order to allow for adequate review and revisions returned by the applicant. Both the research protocols and the adequacy of informed consent must be reviewed at least annually. Meeting dates are announced for the entire year at the start of each new academic year and can be found on the Master Calendar and on the La Verne IRB website.

Turnaround Time 1

Period of Approval:

The La Verne IRB will monitor all approved studies on an ongoing basis. The La Verne IRB will determine in each individual case how frequently a project will be reviewed based on the degree of risk to human participants involved. The typical time period is one year for expedited or standard category applications and may be less frequent for exempt category applications (exempt are currently not under continuing review). Both the research protocols and the adequacy of informed consent must be reviewed at least annually. Reviews may be conducted more or less frequently as determined by the La Verne IRB, and research operations may be observed by the La Verne IRB at any time.

Investigators must submit progress reports via an extension (typically annually if expedited or standard category application) and according to the frequency determined by the La Verne IRB. Failure to do so may result in suspension of the project. Report format at a minimum includes number of participants enrolled since last approval, notable findings, problems in enrollment or retention of participants, and adverse event reports.

Turnaround Time 2