University of La Verne Institutional Review Board
Policy and Procedure on Clinical Trials and
Health Outcomes Research
Approved May 2015

All ULV IRB applications that fall under the category of "clinical trial" research will need to provide the following 2 items in the IRB application.
What is "clinical trial" research?

- A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

1. Confirm all investigators including students understand the liability associated with diagnosis when assessing health outcomes.

- This statement can be included in on the IRB application for review.
  - *All researchers/investigators involved in the research understand they are not licensed to diagnose medical conditions and any/all participants will be referred to a medical professional or agency for further consideration of the medical condition being evaluated within the research protocol.*

2. Confirm associated investigators or medical professionals/affiliate carry liability insurance coverage

- Investigator or Medical Professional/Affiliate Liability Insurance Coverage
  - Investigators or the medical professionals/affiliates associated with the clinical trial should provide professional liability insurance and coverage should be confirmed in the IRB application. The greatest risk during a trial is to inflict bodily injury to a participant and insurance carriers provide policies to cover both the bodily injury (malpractice) and financial loss arising out of a clinical trial.