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 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.