



# Office of Human Research Ethics Training Tips

## Primary Reviewer Presentation Tips for Amendments

November 2014

### **UNC SOP 9.2: Amendments or Modifications**

Amendments or modifications are changes to a previously approved study. Amendments or modifications are reviewed in the same way a new study is reviewed, which may be by the convened IRB or by expedited review, depending on how the changes affect the protocol. For more information on amendments or modifications see SOP 16.0.

### **UNC SOP 16.0 Modifications to Previously Approved Research**

#### 16.1 Modifications to approved protocols

- IRB review and approval is required before investigators can modify research protocols, except when necessary to eliminate apparent immediate hazards to the subjects.
- Full Board Review Criteria:
  - Modifications that increase the risk to subjects or represent a substantive change;
  - A primary reviewer reviews the amendment using the same 111 Criteria as used for initial reviews. Substantive modifications should also receive adequate scientific/scholarly review prior to or in conjunction with IRB review (see SOP 24.2).
  - If the modification involves any new findings, the primary reviewer should include in their recommendation and the IRB will determine whether the change requires re-consenting of all study participants to inform them of the change(s).
- **Exception**
  - If an amendment is needed to eliminate immediate hazard(s) to subjects the investigator should make the necessary change. Within five (5) business days of making the change the investigator should describe the change using the modification form, which will be reviewed by the IRB Chair to determine if a change in risk has occurred in the research and if further changes are warranted.