OHSU Policy

1. It is the responsibility of the Principal Investigator not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the subject.

2. Planned changes to the IRB-approved protocol, i.e., protocol deviations and protocol exceptions, must be submitted as formal protocol amendments (may be termed protocol exceptions if there is no change in protocol) to the IRB and must be approved prior to initiation or implementation of the change.

3. PI will report all protocol deviations per the required reporting procedures.

Effective 1/16/08