Health Sciences IRBs Submission Process for Changes of Protocol
April 10, 2012

PI submits application for scientific and IRB review process. Applications routed by Health Sciences IRBs Office.

If scientific review required, this occurs before IRB Pre-review.

If no scientific review required or scientific review committee agrees study is ready for IRB review, IRB staff pre-review study.

Review by IRB

If scientific review required, modifications may be requested and need to be resolved before study can be moved to IRB pre-review.

Modifications may be requested and need to be resolved before study can be scheduled to IRB for review.

Modifications may need to be resolved before final IRB approval of study can be granted.

 Those protocols that qualify for review by the Western IRB follow a separate process.

Protocol that fall under VA purview require VA Research & Development Committee endorsement prior to being forwarded for formal IRB review

Protocols that fall under VA purview require VA Research & Development (R&D) Committee approval after convened IRB review. The IRB places an administrative hold on VA studies. VA R&D approval is needed to lift the IRB’s administrative hold.