Assessments/Audits

Effective Date: August 27, 2008
Original Approval Date: August 27, 2008

Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

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1.0 Purpose

The IRB’s policy is to comply with all applicable local, state, and federal regulations in the conduct of research studies. The Institutional Review Board (IRB) has the responsibility and authority directly to observe ongoing research projects and the consent process, as well as conduct continuing review of the project, including assessments/audits of research records.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.

3.0 Policy/Procedure

On-site reviews are conducted as part of the Human Research Protection Program’s (HRPP) continuing compliance oversight in accordance to federal regulations.
The review allows the IRB to monitor the implementation of approved protocols, identify areas that need improvement, provide education, and to gather information for continuous improvement on the IRB processes. For routine reviews, studies are randomly selected generally in association with the time of the continuing review. Reviews may also be initiated for cause or by the board.

Investigators are notified, generally by e-mail, to arrange a time to conduct the audit. The earliest mutually agreeable time is arranged to conduct the review, typically within two to ten days. Studies involving VA participants, resources or VA personnel will be reviewed in conjunction with the VA Associate Chief of Staff for Research and Development (ACOS/R&D).

Investigators are notified that some of the items that may be reviewed during the process include but are not limited to:

- Investigator copies of IRB records
- Protocols
- Investigator Brochures
- Subject records (consents, screening logs, accrual, eligibility criteria, etc.)
- Data collection tools/procedures
- Test article/drug accountability
- Regulatory files
- Study related correspondence
- Documentation
- Adverse events and unanticipated problems
- Observe the informed consent process

Assessments are viewed as an educational opportunity for both the IRB and investigators while ensuring research compliance. Investigators and study personnel are encouraged to ask questions or express ideas/concerns.

A written report will be issued within ten days following the review indicating any required corrective actions or education. Any actions that may need to be addressed should be completed within two weeks of the report. Education to address any issues may be provided at the time of the review or if the investigator prefers another date will be arranged. A final report will then be issued.

If the continuing review goes to the convened IRB meeting, a copy of the written report is sent with the continuing review. The board will receive a list of all other reviews conducted during the previous month as an attachment to the minutes and agenda. Board members may request a copy of reviews associated with expedited continuing reviews or Exempt annual updates. The board will be informed of any concerns or issues requiring corrective action.