



Post Approval Monitoring Process

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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 University of Missouri 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 of the IRB processes.

In addition it allows identification of areas within the HRPP that may need to be addressed to increase compliance, quality, and efficiency.

The review process allows the IRB to assess:

- Investigator compliance with policies and procedures
- Areas of needed education for investigators, study staff or departments
- Areas of education that may warrant list serve messages, presentations or changes to forms or policies
- Timeliness of staff responses to investigators/study personnel and/or of IRB review
- Completeness of documentation in eCompliance
- Appropriate consideration and documentation for protecting vulnerable or potentially vulnerable populations
- Timeliness of continuation review of approved research
- Appropriate documentation for and approval of waivers of informed consent and/or alteration of elements of informed consent
- Appropriate inclusion of all the elements of informed consent as required by the IRB/Harry S Truman Veterans Affairs Medical Center (HSTVAMC)
- Appropriate consideration for data and safety monitoring
- Completeness of IRB minutes
- Proper use of expedited and exemption categories

Reviews are considered 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.

Procedure:

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 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
- Observation of the informed consent process

Outcomes:

A written report will be issued within ten days following the review indicating any required corrective actions or education. Education to address any issues may be provided at the time of the review or if the investigator prefers another date will be arranged.

If the review is done in conjunction with the continuing review, a copy of the written report is sent with the continuing review. If the review requires a corrective action requiring full board review, it will be sent to the next available board meeting. The board will make a determination of any required actions and the investigator will be notified in writing after the board meeting.

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 any reviews conducted.

These reviews are part of our quality improvement plan that assesses the quality, efficiency, and effectiveness of the HRPP.

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