Post Approval Monitoring Process

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Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

1.0 Purpose

The HRPP 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 with federal regulations and institutional requirements. The review allows the HRPP to monitor the implementation of approved protocols, identify areas that need improvement, provide education, and to gather information for continuous improvement of the IRB/HRPP processes. In addition, it allows identification of areas within the HRPP that may need to be addressed to increase compliance, quality, and efficiency.

Reviews are either conducted by HRPP/IRB staff or peers that are part of a research tracer team.

The review process allows the HRPP 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 continuing 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/HRPP 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. 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 review. The earliest mutually agreeable time is arranged to conduct the review, typically within two weeks after receiving notification.

Investigators are notified some of the items below may be reviewed during the process:

- Investigator copies of IRB records
- Training and licensing documentation
- Protocols and amendments
- Investigator Brochures
- Package Inserts
- Subject records (consents, screening logs, accrual, eligibility criteria, etc.)
- Data collection tools/procedures (case report forms)
- Test article/drug accountability
- Regulatory binder
- Study related correspondence
- Adverse events and unanticipated problems
- Observation of the informed consent process
- Certificate of Confidentiality
- FDA related documents
- Other documents as requested

Outcomes:

A report will be issued 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 non-compliance or other IRB reportable issues are found, the investigators will be asked to submit an Event Report within 5 business days of becoming aware of the issue.

If the review is completed in conjunction with the continuing review, a copy of the written report is attached to 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.

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.

References:

Policy Revision Dates Prior to January 21, 2019:
August 27, 2008; August 12, 2010; July 1, 2011; July 2, 2014; March 1, 2015; July 1, 2015; June 8, 2017