University of Missouri-Columbia
Human Research Protection Program/Institutional Review Board
Post Approval Monitoring Process Policy

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 and remote (virtual) 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 HRPP/IRB processes. In addition, it allows identification of areas within the HRPP that may need to be addressed to increase compliance, quality, and efficiency.

Reviews may be conducted because the board and/or IRB administrative office required monitoring of the research and/or of the consent processor (for-cause) or may be conducted as part of the HRPP's routine/random selection process (not-for-cause). Investigators are notified by e-mail about for-cause monitoring as soon as a decision is made about the requirement. Documentation is placed within the eCompliance system.

When necessary, the HRPP may review studies in conjunction with the School of Medicine (SOM) Clinical Research & Trials Support Office (CRTSO).

The HRPP team utilizes post-approval monitoring checklists/forms to complete the review. Upon request, the HRPP will share these forms to assist investigators in preparation of the review.

The review process allows the HRPP to assess compliance areas such as:

- Investigator compliance with policies and procedures.
- Areas of education for investigators, study staff or departments.
- Timeliness of staff responses to investigators and/or of IRB review.
- Completeness of documentation in eCompliance.
- Appropriate consideration and documentation for protecting vulnerable or potentially vulnerable populations.
- Appropriate documentation of FDA determinations.

- 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.
- Compliance with the Harry S Truman Veterans Affairs Medical Center (HSTVAMC) research requirements (See the MU HRPP/IRB Truman VA Hospital Human Subjects Research – Special Considerations SOP for additional information).
- Appropriate consideration for data and safety monitoring.
- Completeness of IRB minutes.
- Proper use of expedited and exemption categories.

Reviews are considered an educational opportunity that reinforce best research practices for both the HRPP/IRB and investigators while ensuring research compliance. Investigators and study personnel are encouraged to ask questions or express ideas/concerns regarding the HRPP, including the ethics review process. The HRPP/IRB has open communication with investigators under its oversight and are responsive to questions, concerns, and suggestions.

Notification of Review:

Investigators are notified their study was selected to undergo post-approval monitoring, 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 30 days after receiving notification.

The review evaluates areas such as, but not limited to, the following:

- Regulatory and IRB documentation;
- Protocol adherence;
- Participant recruitment, selection, and payment procedures;
- Participant enrollment and corresponding records;
- Informed consent procedures;
- Participant payment;
- Document and data retention and storage practices;
- Confidentiality and privacy practices and processes;
- Clinical trial requirements; and
- Corrective action plans implementation and adherence.

All research records must be accessible for inspection and copying (by authorized representatives of the HRPP/IRB) at reasonable times and in a reasonable manner. Unavailability of research records or a non-response will result in noncompliance and the MU HRPP/IRB Noncompliance SOP will be followed. Not only are investigators required to respond to and work with the HRPP monitoring team, but they must also fully cooperate with all monitoring activities conducted by the IRB, regulatory agencies, study sponsors, and other institutional requests such as the SOM CRTSO.

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 major non-compliance or unanticipated problems are found, the investigators will be asked to submit an Event Report within 5 business days of becoming aware of the issue. If noncompliance, not rising to the level of major noncompliance, is found, the investigator may decide not to wait until the Annual Update to submit their corrective action plans and submit on the Monitoring Report form in eCompliance. Reporting this type of noncompliance can be done on either the Monitoring Report form or Annual Update form. See the MU HRPP/IRB Noncompliance SOP and Unanticipated Problems SOP for additional information about the submission and review process.

The investigator must address all required actions within the required reporting timeframes outlined in the monitoring report. The HRPP monitoring team will monitor the submission of the required items, then officially close out the post-approval monitoring activity when all items have been addressed.

Copies of the HRPP monitoring report are maintained in eCompliance. There are two versions of the report. One with notes made by the HRPP monitoring team, and one final copy that is redacted and shared with the investigator and uploaded to the attached files in eCompliance.

If the outcomes of the monitoring visit requires full board review prior to sharing the monitoring report with the investigators, 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, and they are also uploaded to the board meeting documents in eCompliance as soon as they are finalized.

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

Effective and Revision Dates:
January 21, 2019; March 23, 2022; August 14, 2024

Approved By: Michele Kennett, JD, MSN, LLM, PhD, Associate Vice Chancellor for Research and Institutional Official

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