Title: Post-approval Monitoring

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<th>SOP #</th>
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<td>HRP-028</td>
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Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC

Approved: Richard Larson, MD PhD, Vice Chancellor for Research

1 PURPOSE

1.1 This procedure describes the processes by which the HRPO monitors an approved research study or an investigator.

1.2 The process begins when the Institutional Official (I/O) or designee, HRPP Director, HRRC Manager, HRRC Chair, or HRRC determines that the research should be monitored to validate that the research is being conducted in accordance with regulatory standards and the HRRC approved research plan or that no material changes have been implemented without HRRC approval.

1.3 The process ends when the HRPO staff have communicated the results to the PI and the I/O, HRPP Director, HRRC Manager, HRRC Chair, or HRRC, as appropriate.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Updated entire SOP to reflect current procedures.

3 POLICY

3.1 Post-approval monitoring provides a means for the HRRC to obtain a direct and independent assessment of compliance with the protocol and regulatory requirement; and to ensure data integrity and patient safety, welfare and confidentiality.

3.2 Monitoring may be classified as routine (part of the normal oversight process), "for cause", or risk-based. Monitoring may be study-oriented (focused on a specific study or a specific aspect of a study) or investigator-oriented (focused on all the studies of a particular investigator).

3.3 HRPO has the authority to monitor any human subject research overseen or conducted by UNMHSC and that the HRRC has the authority to monitor or otherwise observe non-exempt human subjects research under its oversight.

4 RESPONSIBILITIES

4.1 HRPP Director with assistance from HRPO staff and/or a representative or subcommittee of the HRRC.

5 PROCEDURE

5.1.1 Monitoring will be conducted by designated HRPO senior staff.

5.1.2 Monitoring may be initiated in response to the following findings (but not limited to):

5.1.2.1 Allegation of or evidence suggesting noncompliance with applicable regulations or institutional policies or noncompliance with policies of the HRRC

5.1.2.2 ongoing research identified as not being approved by the HRRC
5.1.2.3 Expressed concerns by the sponsor regarding the investigator or the study
5.1.2.4 A complaint from a study participant
5.1.2.5 Investigators conducting multiple studies with questionable time accounting/ allocation
5.1.2.6 Questionable or inconsistent safety/ efficacy findings
5.1.2.7 Unsubstantiated or questionable subject demographics
5.1.2.8 Concerns about subject confidentiality practices
5.1.2.9 Allegations or evidence of scientific misconduct
5.1.2.10 Allegations or evidence of abuse of research participants
5.1.2.11 Evidence or allegations of non-compliance

5.1.3 Upon selection for monitoring the principal investigator will be notified in writing two weeks in advance regarding the selection of his/her study for review. If circumstances warrant, monitoring may be initiated without prior notice. This notification will include the name of the HRPO contact person that will be coordinating the visit.

5.1.4 HRPP Director with assistance from HRPO staff and/or a representative or subcommittee of the HRRC will determine the scope of the audit. The materials to be reviewed and any interviews that will be conducted will be determined based on the scope of the audit but may include, but is not limited to HRRC files, investigator files, and correspondence.

5.1.5 A draft report of the monitoring findings will be provided to the investigator, and the investigator will be provided the opportunity to provide clarifications or additional information in advance on finalizing the report.

5.1.6 Any information that indicates that subjects may be at immediate risk will be immediately reported to the HRPP Director, IO, and/or HRRC Chair:
- When information suggests that serious or continuing noncompliance may have occurred that it will be reported to the HRPP Director and/or HRRC Chair who will determine appropriate next steps including, but not limited to, referring the findings to the HRRC or external IRB of record, if applicable, for review.

5.1.7 For VA research, the findings will be referred to the ACOS for Research and Development or the Research Compliance Officer (RCO). Investigators will be informed in writing within 10 working days.

5.1.8 Post-approval monitoring activities will be documented as part of the study record.

6 REFERENCES
6.1.1 45 CRF 46.109(e)
6.1.2 VHA Handbook 1200.5
6.1.3 AAHRPP 1.3B.id; 1.3B.8; 1.3L.2a,c