I. Procedure Statement

To describe the preparation, reporting, and procedures to follow prior to, during, and following an internal or external audit, review, or monitoring visit.

II. Definitions

1. Internal Audit/Review: A review of relevant clinical trials research documents, processes, and procedures by an entity within the University of Missouri system. This could include the Health Sciences Institutional Review Board (IRB), MU Health Office of Compliance, MU Internal Auditing, MU Health Research Tracer Team, or other entities within the University of Missouri system seeking further insight into quality of care, research design and conduct, or participant safety and confidentiality.

2. External Audit/Review: A review of relevant clinical trials research documents, processes, and procedures by a federal, state, or other outside agency (excluding the study sponsor). This could include the National Cancer Institute (NCI), National Institutes of Health (NIH), Office for Human Research Protections (OHRP), Department of Justice (DOJ), Office of Inspector General (OIG), as well as other agencies and entities. If the Audit/Review is for the Food and Drug Administration (FDA), please refer to the Core SOP for FDA Inspections which details specific processes and procedures that should be followed for an FDA review.

3. Monitoring Visit: the act of overseeing the progress of a clinical trial, and of ensuring it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice (GCP) and applicable regulatory requirements. Usually conducted by a sponsor.

4. For-Cause: A review that is being conducted because information discovered or reported results in a concern regarding noncompliance, data discrepancies, concerns over ethical conduct, or undue risk to research participants.

5. Routine: An audit or review which is an expected component of normal clinical trials research.

6. Case Record/Report Form (CRF): a printed, optical, or electronic document designed to record all protocol required information to be reported to the sponsor on each trial subject. Can also be utilized for investigator/department sponsored projects.
Title: Core Standard Operating Procedure for Internal & External Reviews including monitoring visits

III. Procedure/Content/Scope

This SOP will apply to all clinical trials research within MU Health including the School of Medicine, School of Health Professions, School of Nursing, and MU Healthcare.

1. Determine the type of audit (internal, external or monitoring visit) and the level of severity (routine or for-cause). Any audit that is for-cause should be communicated with:
   a. Principal Investigator (PI)s
   b. Research manager or coordinator
   c. Dean of the appropriate School or CEO of MU Healthcare
   d. IRB
   e. Office of Compliance
   f. Department Administrator
   g. Investigational Pharmacy if applicable

2. Routine audits/reviews (internal or external) should be communicated with the stakeholders listed below. Information shared should include purpose and scope of review, possible dates of review, and names of any individuals that will be on the review team:
   a. Principal Investigator(PI)s
   b. Research manager or coordinator
   c. Research staff if applicable
   d. Investigational Pharmacy if applicable
   e. If an external, routine audit/review, please alert the IRB

3. Monitoring visits scheduled by the sponsor should be communicated with the stakeholders listed below:
   a. Principal Investigator(PI)s
   b. Research manager or coordinator
   c. Research staff if applicable
   d. Investigational Pharmacy if applicable

4. Dates for the audit/review/visit should be scheduled when the PI(s) and pertinent research staff are available and a dedicated room should be reserved for the length of time requested by the review team with the required equipment.

5. All relevant research documentation should be complete and readily available including, but not limited to:
   a. Informed Consents/Subject Binders
   b. Regulatory Binder
   c. Monitoring Visit Log
   d. Device or Drug approvals and logs
   e. Billing Compliance documents
   f. Source Documents
   g. IRB approval letters
   h. Approved Protocols and Consent documents
   i. Compensation Logs
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6. The audit/review/visit team will need access to research data, medical records, and access to electronic medical records. An external review team will need to complete an External User Confidentiality Agreement Form.

7. With respect to external audits/reviews, prior communication with the team should include arrival times, name of the MU Health personnel that will be escorting the audit/research team to the appropriate location, and information about the ability of the audit/research team to accept meals or food.

8. For monitoring visits, ensure the monitor signs the monitoring visit log.

9. At the completion of the audit/review/visit ensure any outstanding or corrective action items are addressed in a timely manner. Necessary information should be relayed to the sponsor and/or monitor. The review team/agency/sponsor will send a follow-up letter following the audit/review/visit. Forward the letter to the IRB and file in the regulatory binder.

IV. REFERENCES:

1. Core Standard Operating Procedure (SOP) for FDA Inspections.