In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR ROUTINE AND FOR-CAUSE AUDITS

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1. PURPOSE

This SOP describes what an investigator should expect during a SERU audit

2. SCOPE

This SOP applies to all Investigators of SERU-approved studies who at any one time may undergo an audit by SERU

3. INTRODUCTION

SERU may perform an audit to evaluate compliance with local and international research regulations and to determine whether a study is being conducted in accordance with the SERU-approved protocol, to ensure adequate protection of research participants.

Audits may involve observation of the informed consent process, observation of study procedures, interactions with participants, interviewing study participants on informed consent process and other study procedures, review of study documents and materials relevant to the conduct of the study among other things. In addition to evaluating the implementation of SERU-approved research, audits may help identify areas for improvement for the researchers, target researchers' training needs and help improve SERU processes.

4. TERMS & DEFINITIONS

4.1 For-cause audit: - this is a systematic assessment of a study(ies) carried out by SERU when a concern or complaint regarding the conduct of a study is discovered or reported to a member of SERU Secretariat/Committee or an administrative official in KEMRI. This type of audit may be focussed on a specific study or on all the studies of a specific researcher. A for-cause audit may be prompted by the following concerns:

4.1.1 Complaints or concerns made by a research participant, family member of the research participant, research team member, an employee or a community member

4.1.2 Studies reporting more than three SUSARs annually, observed among sites in Kenya

4.1.3 Any other concern of relevance

4.2 Routine audit – this is a systematic assessment carried out by SERU to determine whether proper documentation, record keeping, and adherence to local and international regulations are observed in the conduct of SERU-approved research. Studies that meet one or more of the following criteria may be selected for routine audit by SERU:

4.2.1 Recruitment of vulnerable populations or critically ill patients

4.2.2 Rapid accrual of study participants in greater than minimal risk studies

4.2.3 Clinical trials posing greater than minimal risk to participants

4.2.4 P.Is implementing numerous studies concurrently with poor oversight

4.2.5 Studies which report significant unexpected adverse events or serious adverse drug reactions in a number that is determined by the SERU to require frequent assessment.

4.2.6 Studies with multiple arms or multiple and/or complex study procedures.

4.2.7 Studies involving the collection, use and retention of human tissue samples for research purposes.

4.2.8 P.I with a history of repeated non-compliance to local/international regulations as reported to SERU

4.3 Limited Scope Audit - Where a full-fledged audit is not possible or necessary, SERU may conduct limited-scope audits of approved studies to obtain specific information. Such audits may involve one or more of the following:

4.3.1 Request for frequent progress reports from a PI.

4.3.2 Request for a meeting with the PI.

4.3.3 Random inspection of research sites.

4.3.4 Random examinations of research records, including signed informed consent documents, protocol modifications, reports of unexpected and/or serious adverse experiences and sample shipment logs.

4.3.5 Interviews with research participants.

4.3.6 A limited-scope audit may lead to a full-fledged audit as necessary

5. OBJECTIVES

To ensure that research is audited to evaluate compliance with research regulations.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails
6.4 Phone
6.5 Audit plan
6.6 Budget allocation
6.7 Checklists
6.8 Audit documentation

7. EXPECTED OUTPUTS

7.1 Audit report
7.2 CARs

8. KEY PERFORMANCE INDICATORS

8.1 No. of studies audited
8.2 No. of CARs raised
8.3 Time taken to address Non- conformities
8.4 Number of audits conducted

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator: - should avail himself/herself and the research team for a SERU-audit and provide necessary documentation as requested by Auditor

9.2 SERU Committee chair - in conjunction with the Head, SERU make the determination on whether a study should be audited or not as per KEMRI SERU REV SOP 11.0_Study site oversight visits

9.3 Head, SERU - Should inform the P.I of an intended audit in adequate time to allow for adequate preparation

9.4 SERU auditor: - Should obtain the relevant permission from a participant or a participant's parent/guardian prior to carrying out participant observations or interactions with the participant

10. DETAILS OF PROCEDURE

10.1 Prior to the audit

10.1.1 A P.I of a study/studies that have been selected for an audit receives written communication from SERU prior to the commencement of the audit detailing the following:

10.1.1.1 The proposed dates/time and venue(s) of the intended SERU audit

10.1.1.2 The documents required for the audit

10.1.1.3 Duration of the audit visit

(NB: For routine audits, the P.I receives written communication 2-4 weeks before the audit; while for for-cause audits, no advance notice to the P.I is required)

10.1.2 The P.I and the Head, SERU/designee establish an appropriate time and place for the audit to take place.

10.1.3 The P.I makes arrangements to avail all the required documents as well as any other materials/documents that may be necessary for the audit

10.2 During the audit

10.2.1 The P.I receives the auditors from SERU and where possible avails a working space for the auditors

10.2.2 The P.I and auditors hold an inception meeting during which the auditors inform the P.I on the scope of the audit

10.2.3 The P.I avails all the necessary documents, materials, participants and team members for the audit as requested for the following aspects of the audit:

10.2.4 Review of the investigator's site files, participant research records, signed consent/assent forms, source documents and any other relevant records including databases and electronic data

10.2.5 Review of all of the investigator's records to compare with the information submitted to SERU pertaining to that study

10.2.6 Review of study standard operating procedures (SOPs) and other written plans or procedures

10.2.7 Interviews with the P.I, other investigators, study personnel or participants

10.3 Completion of an audit/post-audit

10.3.1 The P.I takes part in an audit closure meeting during which with the auditors may seek further clarification or information or provide a summary of the audit findings

10.3.2 After the audit, the P.I receives a written report on the audit from SERU within 2 weeks of the completion of the audit

10.3.3 The audit report may contain any one of the following outcomes:

10.3.3.1 The audit identified no major problems – no action is needed from the P.I

10.3.3.2 The audit identified problems:

10.3.3.3 The nature of the problems identified

10.3.3.4 The recommended corrective actions/preventive action

10.3.3.5 A SERU Committee determination to suspend or terminate approval to continue with the study as per KEMRI SERU REV SOP 11.0_Study site oversight visits

10.3.3.6 The time-frame within which the P.I should respond to the issues raised or comply with the recommended corrective actions as 2 – 4 weeks from the time they receive the audit report

10.3.4 SERU follows up with the P.I, either through a request for certain documents or a site visit, to determine whether corrective actions have been complied with

10.3.5 Failure of the P.I to comply with the corrective actions may lead to a Committee determination to terminate or suspend SERU approval for continuation of the study

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Routine and for-cause audits	Termination or suspension of	Violation of protocol	To follow the protocol and train the implementing staff on the

	study		protocol.

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Routine and for-cause audits	proper consenting process	Give out information in a simple language to research participant.

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 KEMRI SERU REV SOP 11.0_Study site oversight visits

12.2 External References

12.2.1 ICH GCP https://www.ich.org/fileadmin/Public.../ICH.../Guidelines/.../E6/E6_R1_Guideline.pdf

12.2.2 Helsinki declaration http://www.who.int/bulletin/archives/79%284%29373.pdf

12.2.3 45 CFR 46.109 IRB review of research https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

12.3 Additional resources

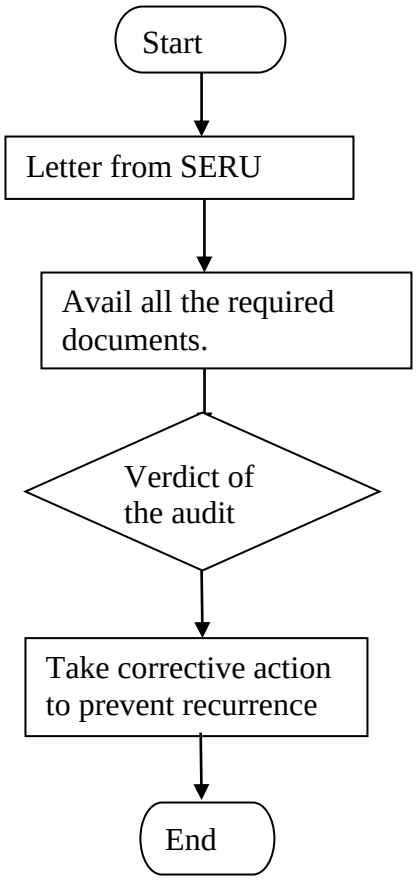
12.3.1 SOP 908 Routine and for-cause audits – University of Utah (https://irb.utah.edu/_pdf/IRB_SOP_908_versionj1911.pdf)

12.3.2 SOP Directed and self-audits http://irb.unm.edu/sites/default/files/406.0%20Directed%20and%20Self-Audits.pdf

13. ANNEXES

13.1 Flow chart Procedures.

ANNEX 1: PROCESS FLOW CHART

Players	Activity	Flow Chart
SERU Auditors	Identify select site for audit Inform Investigator of the intention to audit through written communication Carry Out the Audit Write the Audit Report	
Investigator	Receive the auditors Avail all the required document Take Corrective action to prevent recurrence.	