In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR CLINICAL RESEARCH INVOLVING INVESTIGATIONAL DRUGS AND DEVICES

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1. PURPOSE

The purpose of this procedure (Standard Operating Procedure - SOP) is to describe the submission of research protocols involving clinical trials with investigational drugs/devices.

2. SCOPE

This SOP is applicable to P.Is submitting proposals that entail clinical trials of medical devices and investigational drugs.

3. INTRODUCTION

The SERU requires that P.Is planning to conduct clinical trials involving investigational drugs or devices submit their proposals for initial review and approval to ensure compliance with local and international regulations governing use of investigational products. The P.Is must include a plan to ensure the proper handling of investigational drugs or devices in the initial proposal submission.

4. TERMS & DEFINITIONS

4.1 Drug Used in Clinical Investigation: Any drug, biological, botanical or other substance used specifically for a clinical investigation as described in the investigational protocol. Such drugs shall be either commercially available or not commercially available and used according to, or outside of, FDA-approved indications.

4.2 Sponsor: Means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.

5. OBJECTIVES

To ensure that there is proper handling of investigational drugs or devices in the initial proposal submission.

6. INPUTS/RESOURCES

6.1 Personnel

6.2 Stationery and office equipment

7. EXPECTED OUTPUTS

7.1 Protocol draft

8. KEY PERFORMANCE INDICATORS

8.1 No. of notification requests received

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator – make an application for initial scientific and ethical review of a proposal

9.2 SERU secretariat – receives the application and pre-reviews to ensure that it is complete before including it in a meeting agenda

10. DETAILS OF PROCEDURE

10.1 All initial requests for SERU approval of a study that includes the use of an investigational drug, agent, biologic, or device shall be reviewed and approved by the convened SERU committee.

10.2 An investigator responsible for a study where drugs are stored and dispensed by the study site Pharmacy must abide by the Experts Committee on Clinical Trials (ECCT) of the Kenya Pharmacy and Poisons Board guidelines.

10.3 The investigator must also abide by the Investigator responsibilities for drug studies as outlined in the ICH/GCP E6 guidelines.

10.4 Investigators must submit all information and documents required by SERU for the use of investigational test articles in the initial proposal submission (including, but not limited to, the Protocol, investigators brochure, a site specific addendum/protocol for multi-centre studies where applicable, Informed Consent documents and their translations, Questionnaires or interview guides where applicable, Case Report Forms, etc.).

10.5 Handling of investigational products post-SERU approval

10.5.1 Prescribing

10.5.1.1 Prescribing an investigational drug must be done by an authorized prescriber through the site delegation log as signed and approved by the principal investigator.

10.5.2 Procurement

10.5.2.1 Procurement of an investigational drug must be done by the principal investigator or designated study personnel only after the protocol has been approved by the SERU and the Kenya Pharmacy and Poisons Board.

10.5.3 Receipt

10.5.3.1 Investigational drugs may only be received by the principal investigator or designated study personnel at a designated pharmacy/research clinic.

10.5.3.2 Upon receipt of the investigational drug, the principal investigator or designee will inventory the shipment to ensure that the information on the packing slip matches exactly with what has been shipped, including lot numbers and quantity.

10.5.3.3 Packing slips and documentation of inventory must be maintained with the study records.

10.5.4 Storage/Labelling

10.5.4.1 Investigational drugs used in conjunction with a research protocol must be kept in a locked and secured area and must be clearly labelled

10.5.4.2 Any other information pertinent to administration of the Investigational Drug may also be included on the label (e.g. expiration date).

10.5.4.3 Labelling for outpatient Investigational Drugs must include: subject study identification number, date dispensed, and prescription number, study drug name, directions for use and quantity dispensed.

10.5.4.4 Access to investigational drugs must be limited to personnel designated by the principal investigator.

10.5.5 Dispensing

10.5.5.1 The investigational drug may not be given to anyone not enrolled in the study.

10.5.5.2 The principal investigator must not supply the investigational drug to any unauthorized person.

10.5.5.3 Dispensing of the study drug must be done by a trained and qualified person authorized by the principal investigator as per the delegation log.

10.5.5.4 For accountability purposes, an investigational drug accountability log(s) must be kept for all investigational drug studies. Documentation of the following elements shall be recorded for each drug used:

10.5.5.4.1 Name of principal investigator

10.5.5.4.2 Name of study drug

10.5.5.4.3 Protocol title

10.5.5.4.4 Drug dose, form and strength

10.5.5.4.5 Expiration date of the drug

10.5.5.4.6 Research subject study ID number

10.5.5.4.7 Date dispensed

10.5.5.4.8 Quantity dispensed

10.5.5.4.9 Dose

10.5.5.4.10 Date returned

10.5.5.4.11 Quantity returned

10.5.5.4.12 Balance

10.5.5.4.13 Lot Number

10.5.5.4.14 Signature and/or initials of staff member

10.5.6 Personnel may not remove any drug(s) from the standard drug inventory and substitute them for an investigational drug, even if the drug, under study, is approved and used in practice.

10.5.7 Maintaining a Drug Accountability Log

10.5.7.1 Investigational drug logs must be maintained with the study's regulatory records for the period of time required by protocol or terms of the agreement with the sponsor, whichever is longer.

10.5.7.2 The full names, titles/positions, signatures and/or initials of all personnel responsible for maintaining or documenting in the log(s) must be indicated on either a cover sheet or in the log itself.

10.5.7.3 The principal investigator or designated study personnel must regularly review the drug logs to ensure that there is an adequate amount of drugs available to conduct the study procedures.

10.5.7.4 Drug records must show the receipt, shipment, or other disposition of the investigational drug.

10.5.7.5 The disposition of the drug, including dates, quantity and use by research subjects must be recorded.

10.5.8 Disposition

10.5.8.1 Upon conclusion or termination of the clinical investigation, or by the sponsor's request, the principal investigator shall return to the sponsor any remaining supply of the investigational drug or otherwise dispose of the drug as the sponsor directs. The investigational drug should not be disposed of by the principal investigator or study personnel without obtaining advance written permission from the sponsor.

10.5.8.2 Documentation of why, when, and the personnel involved is required.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Clinical Research Involving Investigational drugs and devices	Access to investigational drugs/device by unauthorized persons	Failure to keep product in a secure location	Ensure investigational product is kept in a locked and secure area

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Clinical Research Involving Investigational drugs and devices	Availability of secure areas to store Investigational drug/device	Train study staff on appropriate storage of investigational drug/device. Providing a specific secure area for storage

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 ECCT guidelines (Guidelines for conduct of clinical trials in Kenya) apps.who.int/medicinedocs/documents/s21351en/s21351en.pdf

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

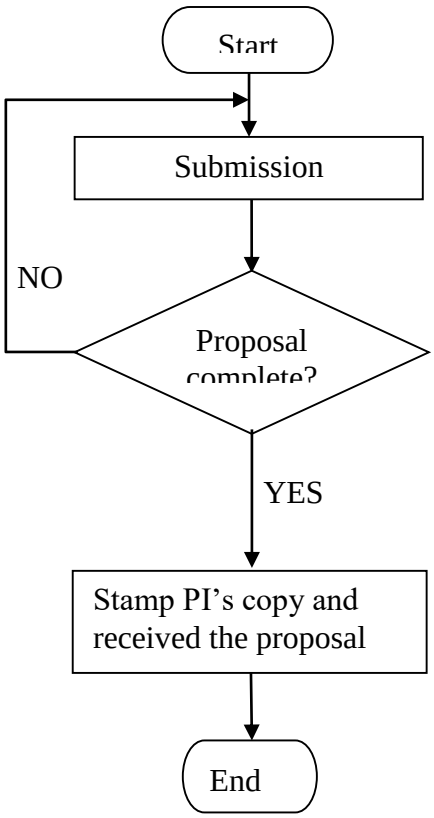
12.2.3 Helsinki declaration

12.2.4 http://www.who.int/bulletin/archives/79%284%29373.pdf

13. ANNEXES

13.1 Process flow chart

ANNEX 1: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting requests for SERU approval of a study that includes the use of an investigational drug, agent, biologic, or device	
Centre Compliance Officer	Do preliminary review of the documents	
Centre Compliance Officer	Forward it to be included in a meeting agenda	