In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR RESEARCH COMPLAINTS AND CONCERNS

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1. PURPOSE

This standard operating procedure (SOP) addresses the process of submitting complaints and concerns about the conduct of a research study.

2. SCOPE

This SOP is applicable to complaints or concerns about research conduct of studies undertaken by KEMRI researchers or SERU approved studies. Research participants, study personnel, investigators or any other relevant members of the public at large may submit complaints or concerns to SERU.

3. INTRODUCTION

The Scientific and Ethics Review Unit (SERU) is committed to the protection of research participants. Research participants are encouraged to express any concerns or complaints regarding the involvement in a research study. Consent documents must include the investigator's contact information for any questions, complaints and/or concerns the participant or legal representative may have about the research or related matters.

Consent documents must also include contact information for the SERU secretariat, this contact information is made available for the reporting of questions, complaints and/or concerns. Information about how to report complaints or concerns is also provided on the SERU website.

The SERU will investigate all complaints or concerns received regarding research conducted under its jurisdiction. All complaints or concerns will be handled in a confidential manner. This includes any reporting of an alleged violation of investigator compliance.

4. TERMS & DEFINITIONS

4.1 Complaint- a statement expressing discontent, displeasure or unsatisfactory service

4.2 Concern- an expression of unease, worry or anxiety about an issue

4.3 Research conduct- the practice of scientific investigation including ethical considerations on the practicality of such an undertaking

4.4 Responsible conduct of research (RCR)- the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

4.5 Consent-Voluntary permission or agreement to participate in research

5. OBJECTIVES

To ensure that research complaints and concerns are documented and appropriate measures are taken to address the issues.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Email
6.4 Phone

7. EXPECTED OUTPUTS

7.1 Feedback to complainant or participant
7.2 Record of complaints and concerns.

8. KEY PERFORMANCE INDICATORS

8.1 No. of complaints received
8.2 No. of complaints resolved

9. RESPONSIBILITY AND AUTHORITY

9.1 Research participant- to lodge their complaints and concerns regarding research conduct.
9.2 Principal Investigator_: - to ensure that this SOP is adhered to and submissions to SERU are done in line with SERU reporting procedures**.**

SERU Secretariat: - to handle the complaints, gather information from the complainant for record keeping and make an inquiry into the circumstances with the study Investigators to take appropriate measures to address the issue.

10. DETAILS OF PROCEDURE

10.1 A research participant or anyone with a concern, complaint, or question regarding a research study involving human participants may raise the concern, complaint, or question with the PI/designated study contact person.
10.2 Gather the following information from the complainant as appropriate:
10.2.1 Participant's (or complainant's) name, and phone number (This information is NOT MANDATORY, and an individual may report an incident anonymously; however, advise the individual that a thorough review may not be possible, and that, without this information, follow-up responses to the individual are not feasible.);
10.2.2 Study protocol title (or acronym) and the name of the PI;
10.2.3 Date(s) of the incident, and;
10.2.4 An explanation of the concern, complaint, or question.

10.3 Assure the individual (or complainant) that SERU will make an inquiry into the circumstances and take appropriate measures to address the issue. Inform the individual of an appropriate timescale for a response or further contact regarding the issue. Explain to the individual the limits to confidentiality.

10.4 Handle the concern, complaint, or question in a confidential manner to the extent allowed by applicable regulations and the law.

10.5 Convey the information regarding the concern, complaint, or question to the SERU, Sponsor, Funder or other relevant stakeholder in a timely manner, where applicable.

10.6 The PI or designee promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issue(s).

10.7 If the alleged impropriety involves potential harm to participants or others, the PI or designee notifies the SERU for immediate action pending formal inquiry**.** The PI or designee reports concerns, complaints, or questions involving serious issues immediately to the SERU on phone: +254 717 719 477 or email: seru@kemri.organd, if appropriate, the institution leadership, study Sponsor and/or Funder.

10.8 The PI or designee manages the inquiry, preparing related correspondence, and maintaining documentation of the issue from reception to resolution. Resolution includes feedback to the participant or complainant.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Research complains and concerns	Research termination or pause	Inappropriate consenting process	Do proper consenting process

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Research complains and concerns	Train field workers in consenting process	Do quarterly trainings on informed consent

12. REFERENCE DOCUMENTS

12.1 External References

12.1.1 45 CFR 46.116(a) General requirements for informed consent: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

12.1.2 221 CFR 50.25(a) Elements of informed consent: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25

13. ANNEXES

13.1 Flow chart Procedures.

ANNEX 1: PROCESS FLOW CHART

Players	Activity	Flow Chart
Complainant /Concerned participant	Raise The Concern, Complaint, Or Question With The PI/ Designated Study Contact Person.	
Principal investigator	Receive complaints and Concerns from different individuals regarding his study Handle the complaints in a confidential manner Convey information regarding the complaint or concern to SERU and other relevant stakeholders. Manage the inquiry, prepare related correspondence, and maintain documentation of the issue from reception to resolution.	
SERU secretariat	Handle the Complaints Gather Information from the complainant and make an inquiry into the Issue. Convey the appropriate Information to the complainant and the Investigator Maintain Documentation of the Issue Conduct Site monitoring visits with the SERU