In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS AND OTHERS

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1. PURPOSE

To provide the procedure for the accurate and timely reporting to the SERU of unanticipated problems occurring in approved research protocols

2. SCOPE

This SOP outlines the reporting requirements and procedures for unanticipated problems as defined below and is relevant to reporting such to the SERU.

3. INTRODUCTION

Institutions are required to have written procedures for "any unanticipated problems involving risks to subjects or others." This SOP addresses that need and delineates how to handle unanticipated problems that need to be reported to the SERU.

4. TERMS & DEFINITIONS

4.1 Unanticipated problems involving risks to participants or others- any incident, experience or outcome that meets all of the following criteria:

- 4.1.1 Unforeseen (not expected by the researcher or the research participant) given the research procedures and the subject population being studied;
- 4.1.2 Related or probably related to participation in the research or the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
- 4.1.3 Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognised.

5. OBJECTIVES

To ensure that the Principal Investigator completes the unanticipated problems form and submit to the SERU.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Logs of unanticipated events

8. KEY PERFORMANCE INDICATORS

8.1 No. of SAE reported

9. RESPONSIBILITY AND AUTHORITY

Principal Investigators (PIs) are required to promptly report to the SERU any event that may represent an unanticipated problem as defined above.

10. DETAILS OF PROCEDURE

10.1 Non-serious unanticipated problems that meet all of the criteria listed above (e.g. negative non-life threatening physical reactions or unanticipated emotional upset, release of personal information/breach of confidentiality) must be reported by the Principal Investigator or study staff within 5 working days of occurrence or identification to the SERU. The Principal Investigator shall complete the unanticipated problems form and submit to the SERU.

10.2 Serious unanticipated problems (e.g. participant death or serious injury to a study participant) must be reported to the SERU by phone: +254717719477 and email: seru@kemri.org within 24 hours of when the study team first becomes aware of the event. The Principal Investigator shall complete the unanticipated problems form and submit to the SERU within 5 working days.

10.3 The Principal Investigator shall promptly respond to all SERU communications, including request for action, information, or instructions.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of unanticipated problems application	1. Miss classification of an event by the Principal investigator 2. Submission of documents that do not meet the criteria for acceptance by the Centre Compliance Officer	1. Principal Investigator failure to correctly classify an event 2. Principal investigator failure to submit all the required documents	1. Attend Trainings

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunities
Submission of unanticipated problems application	Trainings on unanticipated problems application	Attend Trainings

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 KEMRI SERU APP SOP 12.0 Expedited review

12.2 External References

12.2.1 45 CFR 46.103,109 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.103

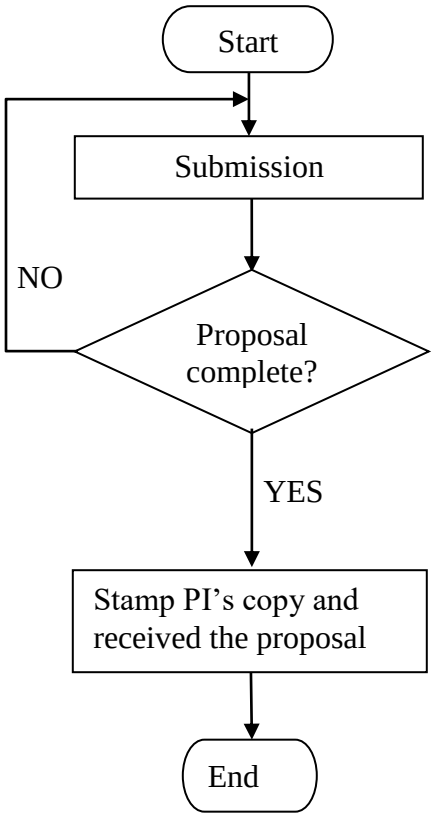
12.2.2 21 CFR 56.108,109 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108

12.2.3 OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects and Others and Adverse Events (Jan. 2007) https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

13. ANNEXES

13.1 Process flow chart

ANNEX 1: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting requests for SERU review of notification	
Centre Compliance Officer	Do preliminary review of the documents	
Centre Compliance Officer	Forward it to be included in a meeting agenda	