In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR

NOTIFICATIONS

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1. PURPOSE

The purpose of this SOP is to outline the procedures to be followed by the Principal Investigator (P.I) for the submission of a study related notification to SERU. Additionally, this SOP defines what is and should be considered a notification submission to SERU and to differentiate notifications from amendments.

2. SCOPE

2.1 The SOP applies to the P.I, the SERU Centre Compliance Officer and the SERU Committee Secretary

2.2 The applications defined as Notifications include;

2.2.1 P.I applications reporting on political instability, financial challenges, equipment failure, addition of Collaborators (not including Investigators),

2.2.2 P.I applications reporting unanticipated challenges regarding the study but not including Safety Reports, Deviations/Violations and Investigators Brochure.

2.2.3 P.I applications not including Investigator changes, alterations on study sites (addition or removal), changes on study procedure, changes on study population or participants, participant reimbursement changes, Addition of a Site Specific Addendum (SSA), or any changes on the methodology of the study

3. INTRODUCTION

Local and International regulations governing research involving human participants, human derived samples, archived biological samples or the use of animals (e.g. mice, rats, primates e.t.c.) require that investigators report to SERU any study related challenges that affect the progress of the study. Historically, confusion has been witnessed regarding what should be reported and what should not be reported. NACOSTI, OHRP, FDA e.t.c. have issued guidance that clarifies what should be reported to SERU (IRB). Therefore, SERU adopts the local and

international guidelines for receiving notifications from the Principal Investigators. Only unanticipated challenges need to be reported.

4. TERMS & DEFINITIONS

4.1 Notification:- this is a report that the P.I submits to inform SERU of a study update, or event, the nature of which does not pose additional risks to the participants nor does it require the Committee's approval for implementation e.g. extra funding for a proposal. Changes that require approval for implementation should be submitted as amendments. Section 3.2 above outlines examples of notifications that P.Is submit to SERU.

5. OBJECTIVES

To ensure that the Principal Investigator sends notifications to the SERU in regards to the study.

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 notifications

8. KEY PERFORMANCE INDICATORS

8.1 No. of notification reported

9. RESPONSIBILITY AND AUTHORITY

9.1 Principal Investigator identifies, prepares and submits a notification application (as per section 1 sub-section 1.2 above) to SERU for review

9.2 P.I to copy the application of Notification application to the study Sponsor and/or funders and include the sponsors/funders in further communications regarding the notification application

9.3 Centre Compliance Officer receives and pre-reviews a notification application as per definition

9.4 SERU Committee Secretary processes the application further.

10. DETAILS OF PROCEDURE

10.1 The P.I identifies a study event/update defined as a Notification as per International and National regulations adopted by SERU and submits five (5) copies to SERU.

10.2 The P.I attaches the latest study approval letter to the Notification being submitted to SERU

10.3 The P.I submits the notification to the Centre Compliance Officer for receiving and pre-review

10.4 The P.I receives a receipt of application acknowledgement from the Centre Compliance Office.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Submitting a Notification	IRB and the Study sponsors being unaware of happenings about the study	Failure to submit notifications to SERU	Train on the importance of submitting notifications.

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Submitting a Notification	Trainings on Notification submission	Participate in trainings on study Notifications.

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

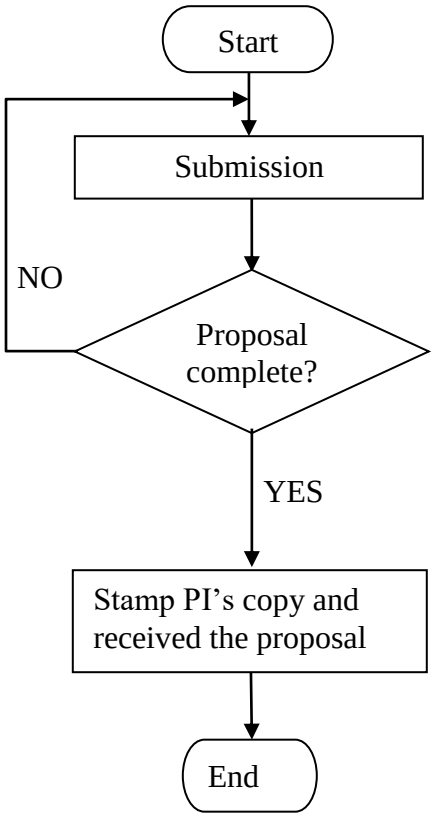
12.2.2 21 CFR 56.108,109 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108

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	