



*In Search Of Better Health*

**K E M R I**

**STANDARD OPERATING  
PROCEDURE FOR AMENDMENTS TO  
RESEARCH STUDIES**



# KENYA MEDICAL RESEARCH INSTITUTE

DOCUMENT TITLE: **AMENDMENTS TO RESEARCH STUDIES**

REF NO: KEMRI/SERU/SOP/PI/AMM

Version: 1

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## Document Control Schedule

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*Controlled copy: Circulation authorized by the Head SERU.*



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## 1. PURPOSE

The purpose of this SOP is to describe what is considered an amendment and the process of amendment submission to KEMRI SERU

## 2. SCOPE

This SOP covers the types of amendment and how their review may be considered.

## 3. INTRODUCTION

A study is normally initially written with an assumption that the final document is practically implementable and complete. However, the investigator may find the need to make a change during the actual implementation stage or a safety concern may arise that necessitates a revision. It is therefore, acceptable to make the necessary adjustments as may be justified

## 4. TERMS & DEFINITIONS

- 4.1 “Protocol amendment” means a written statement that is added to, or revises, or improves an ongoing research study that has obtained approval from SERU.
- 4.2 An amendment is defined as any change to a SERU approved research project, such as:
  - 4.2.1 Recruitment - number of study participants, recruitment methods, recruitment materials, selection of study participants etc.
  - 4.2.2 Research personnel - PI, Co-PI, students or research coordinators or other investigators on the study.
  - 4.2.3 Research sponsor or funding agency.
  - 4.2.4 Study site(s).
  - 4.2.5 Study design including but not limited to study population, methodology, study procedures, sample size, equipment, intervention or follow-up procedures.
  - 4.2.6 Privacy of information or confidentiality of research participants.
  - 4.2.7 Data collection, storage, custody or destruction procedures. This includes revisions to approved questionnaires/surveys or development of a new questionnaire/study instrument.
  - 4.2.8 Informed consent/assent- forms, procedures, new or additional information.
  - 4.2.9 Terms of compensation.
  - 4.2.10 Conflicts of interest(s).
- 4.3 A substantial amendment is defined as an amendment to the terms of the application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:
  - 4.3.1 the safety or physical or mental integrity of the subjects of the study;
  - 4.3.2 the scientific value of the study;



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- 4.3.3 the conduct or management of the study; or
- 4.3.4 The quality or safety of any investigational medicinal product used in the trial.
- 4.3.5 the study objectives
- 4.3.6 the sampling and study design
- 4.4 Non-substantial amendments:
  - 4.4.1 minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
  - 4.4.2 updates of the Investigator's Brochure (IB) (unless there is a change to the risk/benefit assessment for the trial);
  - 4.4.3 changes to the chief investigator's research team
  - 4.4.4 changes to the research team at particular trial sites (other than appointment of a new principal investigator);
  - 4.4.5 changes in funding arrangements;
  - 4.4.6 changes in the documentation used by the research team for recording study data;
  - 4.4.7 changes in the logistical arrangements for storing or transporting samples OR new requests to ship materials out of the country;
  - 4.4.8 Inclusion of new sites and investigators in studies;
  - 4.4.9 Extension of the study beyond the period specified in the application form.

Changes to contact details for the sponsor (or the sponsor's representative), chief investigator or other study staff are minor amendments but should be notified to the SERU committee for information .

## 5. OBJECTIVES

To ensure that the amendment submitted has all the attached documents required.

## 6. INPUTS/RESOURCES

- 6.1 Personnel
- 6.2 Stationery and office equipment
- 6.3 Emails
- 6.4 Checklists

## 7. EXPECTED OUTPUTS

- 7.1 Agenda
- 7.2 Record of received Application

## 8. KEY PERFORMANCE INDICATORS

- 8.1 Number of amendments received



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## 9. RESPONSIBILITY AND AUTHORITY

### 9.1 Principal Investigator

**9.1.1** Submit 5 copies of amended documents and a cover memo explaining the nature of the amendment to SERU.

### 9.2 SERU secretariat

**9.2.1** The SERU Centre Compliance Officer receives, pre-reviews and records all applications submitted to SERU

## 10. DETAILS OF PROCEDURE

**10.1** All principal investigators (PIs) are required to submit any proposed changes to a previously approved study to the SERU committee(s) for review prior to initiation. The only one exception to this rule shall specifically be where the change is necessary to eliminate apparent immediate danger/risk to the research participants. In such instances, the principal investigator must submit a report/notification to the SERU committee explaining the protocol deviation.

**10.2** All requests for a protocol amendment for all approved KEMRI-affiliated studies are forwarded to the SERU committee, by the KEMRI Centre Scientific Committee (CSC) Secretary, for consideration.

**10.3** The request for amending any SERU-approved NON-KEMRI studies should be addressed to the Head, SERU and submitted to the SERU Secretariat directly as it does not need to pass through the KEMRI research centres.

**10.4** The PI submits the completed amendment submission form, the amended protocol, a cover letter outlining the nature of the suggested changes, the justification for the change, and a comment on expected ethical consequences arising from the proposed amendment.

**10.5** The complete application for the amendment is discussed at the next available SERU meeting provided that the request has been received by the deadline for submission.

**10.6** The SERU committee determines whether the amendment is approved as submitted or if further information, clarification or change is required for the evaluation of the suggested amendment and clearly articulates the basis for such a decision to the PI or applicant.



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- 10.7** The SERU Secretariat communicates to the PI, in writing, the outcome of the SERU committee deliberations on the request within six (6) working days of the meeting at which the request for the amendment was considered.
- 10.8** The SERU committee discussions on the amendment request are recorded in the minutes of the meeting.
- 10.9** The Chairperson shall expedite the review of an amendment to an approved protocol if any of the requirements set out in KEMRI SERU APP SOP 12.0\_Expedited review are met.

## 11. RISKS AND OPPORTUNITIES

### 11.1 Risks

Process	Risk	Risk source	Mitigation
Submitting an Amendment	Amendment not being slotted in the Agenda for discussion	Failure to submit a complete Amendment with all the required documentation	Ensure proper use of the Amendment Checklist.

### 11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Submitting an Amendment	Trainings on proper use of the Amendment Checklist	Organizing trainings for the Investigators through their centres or organizations.



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## 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 <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/definitions-of-substantial-and-non-substantial-amendments/>

## 13. ANNEXES

13.1 SERU Amendment Submission form

13.2 Process flow chart



**ANNEX 1: AMENDMENT SUBMISSION FORM**

**KENYA MEDICAL RESEARCH INSTITUTE  
SERU SUBMISSION FORM FOR AMENDMENTS**

**PART A (TO BE FILLED BY THE PRINCIPAL INVESTIGATOR)**

Protocol Title: .....

Last approved protocol Version No. & Date:.....

Centre..... SERU/SSC No: .....

Name of Principal Investigator: .....

Research Programme Area(s): .....

Key Performance Area: .....

Strategy: .....

Millennium Development Goal: .....  
(Please refer to SERU page at [www.kemri.org](http://www.kemri.org) for programmes/ /Key Performance Area/Strategy and MDGs)

Study Implementation County(s): .....

**Protocol Information:**

Date of first approval: ..... Amendment No.:.....

Protocol Version number and date of the current amendment submission:

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**Details of the Amendments requested**

**Justification for the suggested amendment(s):**



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**NB: PLEASE NOTE THAT in general an amendment should only change on of the following i.e. purpose, procedures or population. Any change/amendment that will affect any two of three i.e. purpose, procedures or population, will constitute a new proposal and should be submitted as such. Examples that may need a new proposal: Purpose: the objectives change and Population – the population changes from men to women. Another example methods: the sample size changes and procedure: the inclusion and exclusion criteria changes. This is for general guidance if there are any uncertainties consult SERU on phone or email for clarification prior to submission**

**NOTE: THE TABLE BELOW MUST BE FILLED AND SIGNED BY THE INVESTIGATORS BEFORE FORWARDING BY THE CENTRE**

NAME AND INSTITUTION	TELEPHONE	EMAIL CONTACT	SIGNATURE

## **1.1.1.1 PART B (TO BE FILLED BY THE CENTRE DURING FORWARDING)**

This protocol amendment was forwarded by the Scientific Committee of



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\_\_\_\_\_ (Centre) on

\_\_\_\_\_ (date)

Name: \_\_\_\_\_  
(Secretary, Scientific Committee)

\_\_\_\_\_  
Signature Date

Name: \_\_\_\_\_  
(Chairman, Scientific Committee)

\_\_\_\_\_  
Signature Date

Name \_\_\_\_\_  
(Director of centre)

\_\_\_\_\_  
Signature Date

Notes: **The signed form must be sent to SERU with 5 copies of the protocol to be reviewed. Please use the checklist for submission.**

**Please send only the soft copy, without signatures of this forwarding form, to the M & E Office ([m\\_e@kemri.org](mailto:m_e@kemri.org))**

**ANNEX 2: PROCESS FLOW CHART**

<u>Players</u>	<u>Activity</u>	<u>Flow Chart</u>
Principal investigator	Submits five copies of amendment applications	
Centre compliance Officer	Preliminary review to check if documents is complete. If the document is incomplete it is returned to the PI.	
Centre compliance Officer	Stamps the documents and give the PI completed and stamped acknowledgement of receipt of the submitted documents to SERU	<pre> graph TD     Start([Start]) --&gt; Submission[Submission]     Submission --&gt; Decision{Proposal complete}     Decision -- NO --&gt; Submission     Decision -- YES --&gt; Receiving[Receiving]     Receiving --&gt; End([End])         </pre>