In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR CONTINUING REVIEW

Document Control Schedule

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Signature:	
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1. PURPOSE

The purpose of this SOP is to outline the continuing review process for investigators applying for continuing review/approval to Scientific and Ethics Review Unit (SERU).

2. SCOPE

This SOP covers all the processes and procedures required for an investigator to be granted a continuing approval.

3. INTRODUCTION

Continuing review allows SERU to assure the safety and wellbeing of study participants participating in approved research protocols through giving an opportunity to review the study progress, adverse events and other relevant study documents that guide determination of adherence to ethical standards and compliance with the approved protocols.

4. TERMS & DEFINITIONS

4.1 CRR: Continuing Review Report
4.2 SERU: Scientific and Ethics Review Unit
4.3 SOP: Standard Operating Procedures
4.4 IND: Investigational New Drug/product

5. OBJECTIVES

To ensure that the Continue Review Report 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 No. of Continue Report Requests received

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator- The principal investigator is responsible for submitting the continuation request

9.2 Secretariat- The SERU secretariat receives the application, acknowledges receipt and assigns it to reviewers

10. DETAILS OF PROCEDURE

10.1 The SERU committee shall undertake continuing review of each approved study at least once a year, but may require more frequent reviews, such as, where this is warranted by the level of risk the research presents.

10.2 This review shall be conducted before the anniversary of the previous approval. The investigator shall submit the continuing review request/report to SERU 4 weeks before the anniversary of the previous approval date for studies that don't involve an investigational new drug/product (IND).

10.3 Study protocols/clinical trials with IND/products will need the continuing review request/report submitted 6 weeks before the one-year anniversary of the previous approval date.

10.4 The request for continuing review shall comprise:

10.4.1 Six copies of a duly signed explanatory cover letter (1 will be stamped as acknowledgement of receipt by the SERU secretariat and kept by the investigator as evidence of submission)

10.4.2 Five copies of the annual progress report or status report

10.4.3 One copy of the current approved study documents any publications and/or abstracts (continuing review report (CRR) submission form)).

10.5 All active or open studies must be renewed including:

10.5.1 A study that is closed to accrual of research participants but is in the follow-up phase.

10.5.2 A study in which direct contact with study participants is complete but data analysis, report writing or manuscript preparation are the only on-going activities.

10.5.3 A proposed study that has not been initiated within twelve (12) months from the date of ethical and scientific approval provided that valid reasons for not undertaking the research in the initial approval period have been provided.

10.6 The SERU secretariat assigns a member of the secretariat to each KEMRI centre/non KEMRI protocols. The designated staff member receives continuation review requests (CRRs) and performs an interim review. This review separates the applications into two categories:

10.6.1 Expedited review: Observational studies get expedited review once confirmed that the CRR is in order this is forwarded to a staff member responsible for allocating CRRs for review within the secretariat.

10.6.1.1 Each CRR is allocated to three reviewers and a turnaround time of 3 days is required.

10.6.1.2 After the review, a member of the secretariat generates a combined report and this is submitted to the SERU head for signature, which comes out as approval or disapproval and needing further clarification from the PI.

10.6.1.3 The approved/disapproved CRRs are submitted as a batched report to subsequent SERU meetings and ratified.

10.6.2 Normal review: Clinical trials/studies not meeting expedited review criteria: A secretariat staff member forwards the CRRs to 3 SERU reviewers after confirming the application is in order.

10.6.3 The reviewers submit their comments 2 days before a SERU committee meeting where their feedback is deliberated, captured in minutes and a decision made to approve/disapprove the CRR.

10.7 The continuing review takes into account what was proposed in the protocol and reviews progress against proposed targets.

10.8 If the continuing review does not take place within the timeframe set by the SERU committee, the research study will automatically expire. The principal investigator (PI) shall be required, to immediately submit a list of research participants for whom the postponement of research would

cause harm within five (5) days of expiration. In addition, the PI should also submit a protocol deviation form.

10.9 The Chairperson in consultation with the SERU committee members shall issue an appropriate course of action. The PI may resume the study once continuing review and approval by the SERU committee has taken place.

10.10 The SERU committee(s) discussions on the continuation requests shall be recorded in the meeting minutes.

10.11 The SERU committee(s) shall determine whether further information, clarification or change is required for the evaluation of the report and clearly articulate the grounds for this decision to the PI or applicant.

10.12 The SERU Secretariat shall communicate to the PI, in writing, the outcome of its deliberations on the request within six (6) working days of the meeting at which the request was discussed.

10.13 Any given research study will be renewed at least once every twelve (12) months for the duration which was approved for the given study.

10.14 All approved research protocols shall have a life according to the approved study duration. In addition, renewal requests may be submitted for additional time to allow preparation of the final study report/publications.

10.15 After expiry of the study duration and reasonable time to allow study publications (approximately 3 years) a new research proposal should be developed and submitted for review or an extension be submitted with appropriate justification.

10.16 A final study report should be submitted and notice of closure must be issued on or before the expiry date of final approval..

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Submitting an Annual Renewal	Expiration of the Research study	Failure to submit a an annual renewal request or submission of a CRR without all the required documentation	Ensure proper use of the CRR Checklist. Submission of the annual renewal request 6 weeks to its expiration.

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Submitting an Annual Renewal	Trainings of how to make a CRR Submission and on proper use of the CRR Checklist	Organizing trainings for the Investigators through their centres or organizations.

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

12.2.2 Helsinki declaration http://www.who.int/bulletin/archives/79%284%29373.pdf

13. ANNEXES

13.1 SERU CRR form
13.2 SERU Protocol deviation reporting log
13.3 Process flow chart

ANNEX 1: SERU CRR FORM

KENYA MEDICAL RESEARCH INSTITUTE
SCIENTIFIC & ETHICS REVIEW UNIT (SERU)

Title of Proposal:

_____

Principal Investigator(s):_____

Centre:

_____

SERU/NON-SERU/SSC/NON-SSC No.:_____
(Tick the appropriate identifier)

1) **Date of scientific and ethics (SERU/SSC/NON-SSC)approval:**

   i) **Date the studystopped collecting data where applicable:**
      - ✓ Date for the last participantwas recruited(and enrolment)
      - ✓ Date the last follow up was made.

2. The copy the last continuing review approval or initial approval if this is the first request for renewal:

3.Project period covered: Indicate the project period covered by the report (the period reported cannot exceed one calendar year, in case the reporting period exceeds a calendar year, please fill in a separate form for each year being reported on) e.g. 28 February 2007 to 16 January 2008.

4. **Research objectives:** Briefly describe the purpose of the study.

5. **Research progress summary:** Briefly describe the progress made during the reporting period, highlighting key findings and achievements during the period. Include the number of new study participants enrolled/recruited into the study, the number of study participants continuing participation and the number of new study participants expected to enroll or leave the study during this period and reasons for their departure. Summarize on-going activities

6. **Amendments:** Indicate any amendments made and approved during the reporting period e.g. changes in research site, increase in study sites, sample size, procedure, recruitment plan, investigators, start/end date, modification of informed consent documents, or any other deviation from the original, approved study or protocol violations etc.

7. **Adverse events reports:** If applicable, report any adverse events – expected or unexpected e.g. related to a drug or a product/procedure being tested that may have occurred during the reporting period, the proportion of the study participants involved, the severity and how the events were handled.

8. **Projects outputs:** State if there were any publication, abstract, a product, patent application, etc. during the last calendar year reporting period, please list these and provide details. Please attach anystudy output for the reporting period.

9. **Constraints:** State any constraints experienced during the reporting period, and whether or not they adversely affected project progress. Constraints may include lack of funding, transport, personnel, space etc.

10. **Any other relevant information:** Include any information that might be relevant to this report but not captured in the items listed e.g. if there has been new literature in the field that may or may not affect the conduct of the study or the risk/benefit status of the study. State whether or not a continuation approval is required for the project.

11. **Plans for the next project year:** State project activities planned for the coming year or continuing into the next year. Indicate if this is the last project year.

Checklist for documents submitted by the Principal Investigators:

DOCUMENT	COPIES	CONFIRM
Cover letter	5	☐
Continuing Review Report (CRR)	5	☐
The last SERU/ERC approval letter	5	☐
Current approved Protocol	1	☐

ANNEX 2: PROTOCOL DEVIATION FORM

APPENDIX D: SAMPLE PROTOCOL DEVIATION OR VIOLATION REPORTING FORM

Version Number 4.0
Effective Date: 3 September 2009
Supersedes

Title of Proposal:
Principal Investigator(s)
SSC/NON-SSC No.:

1. Date of Deviation/Violation:

2. Study Participant number (where applicable):

3. Name of treating physician (where applicable):

4. Provide a description of the deviation/violation: State whether the study participants were adversely affected by the deviation/violation; whether the deviation/violation placed the study participants at greater risk and whether the study participants were informed of the deviation/violation, where applicable.

5. Provide an explanation as to why the deviation/violation occurred.

6. Describe the measures taken to address the deviation/violation.

7. Describe the measures taken to preclude future recurrence of the deviation/violation.

8. Indicate whether the study sponsor has been notified.

_____ __ _____

Typed name and signature of the PI Date:

ANNEX 3: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal investigator	Submits all applications for Continue Annual review to the SERU secretariat	
Centre compliance Officer	Does preliminary review on the submitted proposals to ensure all the submitted documents meet the checklist criteria.	
Centre compliance Officer	Stamps the documents and give the PI completed and stamped acknowledgement of receipt of the submitted documents to SERU