In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR STUDY CLOSURE REPORTS

Document Control Schedule

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1. PURPOSE

The purpose of this SOP is to outline the steps to be followed by an investigator when submitting a requesting to SERU to close their study/studies

2. SCOPE

1.1. This SOP is applicable to investigators who wish to submit a close-out request for a SERU-approved protocol for review. The P.I can close the study when the following are completed:

1.2. Research-related interventions/interactions with human subjects

1.3. All data or sample have been collected

1.4. Main data and sample analysis to meet the main study objectives have ceased

1.5. Main study manuscript or report has been published

1.6. The P.I may close the study due to the following reasons:

1.7. Completion of the study as described in the protocol

1.8. Permanent premature discontinuation of the study earlier than anticipated for any reason

1.9. A study is stopped prior to enrolment of the first participant.

3. INTRODUCTION

Principal Investigators (PIs) should notify IRBs of the intended closure of their studies regardless of the reason for closure. A final closure report should be submitted to the IRB overseeing the study in accordance with Good Clinical Practice guidelines.

4. TERMS & DEFINITIONS

4.1 "Study closure – refers to an application by the study P.I to update SERU on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal, information on the final disposition of research records, samples and data, and a request for approval to cease conducting the study. Once approved, a study closure denotes the end of SERU's oversight on that particular study. The P.I should not file a study closure request if any of the following applies:

4.1.1 Enrolment at the study site is ongoing

4.1.2 Research-related interventions and/or follow-up at the study site are ongoing

4.1.3 Participant follow-up at the study site is ongoing.

4.1.4 Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research is ongoing.

4.1.5 Data analysis or manuscript preparation that involves the use or access to personally identifiable information is ongoing.

4.1.6 If there is an external study sponsor and the sponsor has not provided permission to close the study with SERU.

5. OBJECTIVES

To ensure that the close out request 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 studies closed

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator – responsible for submission of a duly completed closure report and accompanying documents to SERU

9.2 SERU secretariat – receives the submission package and pre-reviews to ensure that all the required documents are included in the submission package; ensures the Committee review outcome is communicated to the P.I in a timely manner.

10. DETAILS OF PROCEDURE

10.1 An investigator/designee files a close-out report with the SERU after:

10.1.1 All participant recruitment and follow-up has ceased; or

10.1.2 All study samples have been collected; and

10.1.3 Data has been locked for analysis; and

10.1.4 Research findings have been disseminated through publication of the main manuscript, study report or policy briefs

10.2 The investigator/designee completes the SERU closure report (Annex I) and submits the following accompanying documents, where applicable:

10.2.1 Cover letter signed by the P.I/designee

10.2.2 Copies of publications from the study

10.2.3 Copies of relevant study outputs

10.2.4 Copies of results dissemination reports

10.2.5 Plans of destruction of participant identifiers and an assurance of the destruction of participant identifiers e.g. blacked out names in screening and enrolment logs

10.2.6 Plans of destruction/disposal of investigational products/devices and a certificate of destruction

10.2.7 Plans for destruction of surplus biological specimens and certificate of destruction (indicate how many specimens are being destroyed);

10.2.8 If the study protocol stipulated that the specimen(s) in question would be subject to long term storage and future research:

10.2.8.1 Provide the plan for long-term storage of biological specimens

10.2.8.2 Provide the plan for future use of biological specimens obtained as part of the study

10.2.8.3 Indicate the total number of samples being stored for future use?

10.2.8.4 Provide the plan for the destruction of biological specimens at the end of their use

10.2.8.5 Any other relevant documents as specified in the SERU closure report

10.3 The investigator/designee submits 5 copies of the application package to SERU. (NB: Applications being submitted from KEMRI Centres should be forwarded through the respective centre directors.

10.4 The study closure report is reviewed at the next available SERU committee meeting provided that it is received by the SERU Secretariat on or before the closing date for submission for the meeting.

10.5 The P.I awaits to receive written communication on the review outcome from SERU**.**

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Submitting a Study Close out Request	Rejection of the study close out	Failure to fulfil all the study closure requirements	Training the Applicants on successful closure of studies

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Submitting a Study Close out Request	Training on successful closure of studies	Attend trainings on study closures

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 ICH E6 Good Clinical Practice (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen_en.pdf)

13. ANNEXES

13.1 SERU Study Closure Report form
13.2 Process flow chart

KENYA MEDICAL RESEARCH INSTITUTE

ANNEX 1: STUDY CLOSURE REPORT FORM

A. General Information:	
Principal Investigator:	
Study Title:	
SERU/CSC/SSC/NON-SSC No.:	
Start Date :	**End Date:**

Start date = Date of First approval; Expiry date of last approval;

B. Study Status at Close-out:
[ ] Study was completed [ ] Study was started but closed prior to completion [ ] Study was not started [ ] Study is being transferred to another institution
C. Reason study was not started or was closed prior to completion or is being transferred to another institution:
E. Provide a summary of research objectives:
F. Summary of Study Results: Please summarize the results of this research project, even if only for the study cohort enrolled locally.

G. List publications arising from study (attach copies of the manuscript(s))

I. Confirm destruction of each study participant's identifiers and provide an assurance/evidence that the destruction has occurred (send copies of the blacked out books).

J. Detail the plan for future use of data from the study (if applicable)

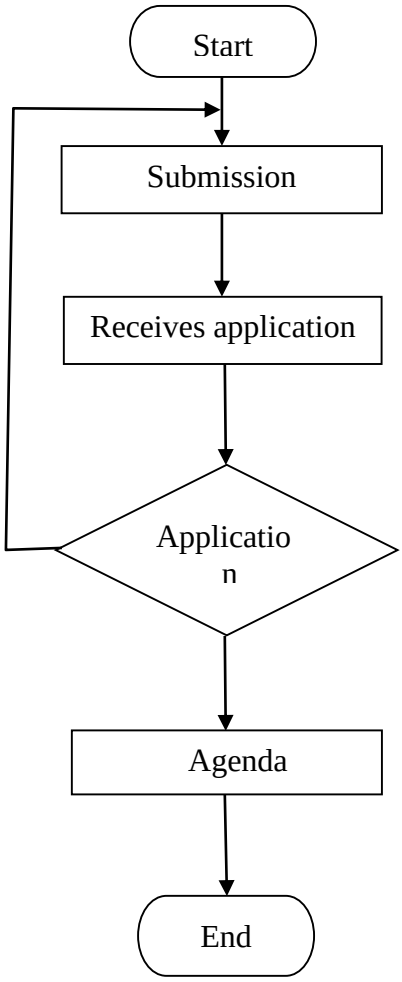
K. Confirm destruction of surplus investigational agents and provide an assurance/evidence that the destruction has occurred (if applicable)

L. Detail the plan for the destruction, storage, or future use of biological specimens obtained as part of this study (include number of samples being destroyed or stored)

_____ _____

Signature of Principal Investigator(s) **Date**

ANNEX 2: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting request for a closure of a research study	
Centre Compliance Officer	Receives, pre-reviews the closure requests	
Centre Compliance Officer	Determine if the application is complete and meets all the requirement	
	The study closure report is keyed into the next open Agenda	