In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR RESEARCH ON ANIMALS

Document Control Schedule

Name of department:	**SERU**
Document Type:	**Management Procedure**
Document Ref:	**KEMRI/SERU/SOP/PI/RON**
Process owner:	**Head Compliance SERU**
Signature:	
Approved By:	**Head SERU**
Signature:	
Effective Date:	**October 18, 2017**

TABLE OF CONTENTS

1. PURPOSE

This SOP describes the procedure adopted for safe and compliant governance of research involving animals.

2. SCOPE

2.1 This SOP applies to the P.I, the SERU Centre Compliance Officer (s), and the SERU Assistant Secretary (s).

2.2 The scope of this SOP also applies to the Animal Care and Use Committee (ACUC) because SERU approval of research involving animals depends upon prior approval by the ACUC.

2.3 Covers all study applications covering research involving use of animals

3. INTRODUCTION

The SERU committee is designated by KEMRI to approve the initiation of and undertake periodic review of all research conducted in the institute including studies involving animals. The Principal Investigator is required to submit a protocol (involving animals) to the KEMRI ACUC before submitting to SERU for further review. Approval letter from KEMRI ACUC should be obtained before the application is submitted to SERU.

4. TERMS & DEFINITIONS

4.1 Animal Care and Use Committee (ACUC) – Undertakes review of protocols involving animals prior to such an application being submitted to SERU for review

5. OBJECTIVES

To ensure research on animals applications are received effectively and efficiently.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 No. of applications received

9. RESPONSIBILITY AND AUTHORITY

9.1 The P.I is responsible for obtaining ACUC approval before submitting an application involving animals to SERU for initial review.

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

9.3 The ACUC reviews and either approves applications involving animals or recommends modifications of the proposal before submission to SERU

10. DETAILS OF PROCEDURE

10.1 The P.I submits an application involving the use of animals to the KEMRI Animal Care and Use Committee (ACUC)

10.2 The P.I, after obtaining ACUC approval, then submits the application to SERU and the SERU committee reviews new research proposals involving animals at its next available meeting.

10.3 The SERU Centre Compliance Officer receives, pre-reviews and either accepts or rejects the application depending on whether it meets criteria for acceptance as per the SERU checklist for initial submissions (Appendix 1).

10.4 The SERU Centre Compliance Officer gives the P.I a stamped acknowledgement receipt for the application that meets the criteria for acceptance

10.5 In its review, the SERU Committee assesses the following:

10.5.1 The justification for the use of animals.

10.5.2 The arguments in support of the chosen animal species or model.

10.5.3 The training and expertise of veterinarians and animal care staff on the study.

10.5.4 The biosafety measures instituted in all aspects of the study.

10.5.5 The potential benefits and harms presented by the study and the possibility of reducing the harms.

10.6 The SERU committee's discussions on the study protocol or application are recorded in the minutes of the meeting.

10.7 The P.I receives, in writing, the outcome of its deliberations on the proposed animal study (or on any amendments to an approved animal study) within six (6) working days of the meeting at which the research proposal or application was discussed.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of Research on animals applications	Rejection of application by the SERU centre compliance officer	Principal Investigator providing inadequate documents	Training of investigators

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunities
Submission of Research on animals applications	Training on Research on animals applications	Scheduling and participating in regular trainings

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 None

13. ANNEXES

13.1 Annex 1 - SERU Checklist for Initial proposal Submission
13.2 Annex 2 – Process flow chart

ANNEX 1: SERU CHECKLIST FOR INITIAL PROPOSAL SUBMISSION

Document	What to check for	Tick box	Hard copies
Cover letter listing documents attached	• Date • Title of study • Type of submission • List of all documents attached (include versions) • Signed by PI or investigator on behalf of PI	☐	5
SERU Submission Form	• SDGs, programme and strategic objectives specified • Counter-signed by PI(s) • Funder and budget specified • CSC Number • Version Number and Date • All signatures obtained and dates are complete and correct	☐	5
Letter from the Secretary, CSC	• Letter to the PI with comments raised by CSC reviewers	☐	5
Protocol	Version Number and Date • Abstract • Lay summary • Document has page and line numbers and version control in header or footer on every page and continuous line numbering • All appendices are listed and included	☐	5
Participant information and Informed consent document(s) ☐ Not applicable	Version: Date: Reading level/Language: • Numbering of appendices should be sequential • Version appears as header or footer on every page • All applicable language translations should be included as separate appendices • Translation & backtranslation certificate included	☐	5
Study tools (KIIs, Questionnaires, FGDs,)	Version: Date: Language: • Numbering of appendices should be sequential • Version appears as header or footer on every page • All applicable language translations should be included as separate appendices Translation & backtranslation certificate included	☐	5

CVs of non-KEMRI investigators	• All non-KEMRI investigators listed on title page and under roles of investigators (check that these two sections match and cross-check with ICDs investigator list) have CVs attached	☐	5
Investigator ethics certificate	• NIH, AMANET, FHI, TRREE or CITI (preferred) course (valid for only two years)	☐	5
Investigator current practising licence	• All clinicians who will have direct contact with participants and those who provide medical consult.	☐	5
Investigators Brochure/Summary of product characteristics ☐ Not applicable	Version: Date: • Applicable pre-clinical and clinical trial safety information pertaining to the investigational product	☐	5
Case report forms/ /eCRF template	• A blank draft copy of the forms that will be used to collect protocol related data	☐	5
Additional requirements for Research involving animals	• Animal Care and Use Committee (ACUC) Approval letter • CVs of veterinary experts • CVs of animal care staff	☐ ☐ ☐	5 5 5
Other approvals ☐ Not applicable	• Letter of scientific review and approval from host institution for Non-KEMRI proposals • Approvals from any other ethics committee • Pest control products board	☐	5
Insurance certificate for clinical trial participants ☐ Not applicable	• Valid cover for participants insuring them against trial related injuries filed in site file where applicable	☐	5
All other relevant attachments	• Recruitment adverts, t-shirts, pamphlets or any other information to the participants about the study that requires approval and local language translations as applicable	☐	5

ANNEX 2: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting research related injury/harm applications	
Centre Compliance Officer	Receives, pre-reviews and records all research related injury/harm applications submitted to SERU