In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR SUBMISSION FOR INITIAL REVIEW OF A PROPOSAL

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1. PURPOSE

This SOP describes the procedures and documents required for the submission of a new protocol for initial review by the KEMRI Scientific and Ethics Review Unit (SERU) committees to ensure that the proposed research adheres to sound scientific and ethical principles

2. SCOPE

This SOP is applicable to investigators or their designees who seek to submit their research proposals for initial review by a SERU Committee. The SOP provides instructions on the documents that need to be submitted to SERU and the procedures to be followed when submitting a proposal for initial review.

3. INTRODUCTION

Research proposals submitted by investigators should contain sufficient information to allow SERU reviewers to determine whether the proposed research is scientifically justified and that it adheres to local and international guidelines on ethical conduct of research prior to approval. The initial review of proposals is required for the approval of any research that meets the definition of research requiring SERU review as outlined in section 4 below.

4. TERMS & DEFINITIONS

4.1 Research: - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

4.2 Human subject: - a living individual about whom an investigator conducting research obtains:

- 4.2.1 Data through intervention or interaction with the individual, or
- 4.2.2 Identifiable private information

5. OBJECTIVES

To ensure that complete submission of initial submission is done.

6. INPUTS/RESOURCES

6.1 Personnel

6.2 Stationery and office equipment
6.3 Emails
6.4 Checklists
6.5 Review Fee for Non-KEMRI

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of received Application
7.3 Payment receipt

8. KEY PERFORMANCE INDICATORS

8.1 No. of new proposals received
8.2 Amount of money raised from Non-KEMRI initial applications

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator/designee – make an application for initial scientific and ethical review of a proposal

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

10. DETAILS OF PROCEDURE

10.1 The Principal Investigator (P.I) ensures the scientific proposal contains all the relevant scientific and ethical aspects as per the KEMRI SERU proposal format (Appendix 1: KEMRI SERU proposal format)

10.2 The P.I completes the KEMRI SERU proposal submission form (Appendix 2:_SERU proposal submission form)

10.3 The P.I submits all the relevant documents as per the SERU checklist for submission of new proposals (Appendix 3_SERU Checklist for initial proposal submissions)

10.4 The P.I submits all applications for scientific and ethics review to the SERU secretariat on or before the closing date for each committee as posted on the SERU website.

10.5 The P.I receives a completed and stamped SERU proposal submission checklist, either in hard-copy or as a scanned copy via email, as acknowledgement of receipt of the submitted documents by the SERU Secretariat

10.6 All P.Is submitting non-KEMRI proposals must attach a letter of scientific review and approval of their proposals from their host institution or another reputable institution.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission for Initial Review of a Proposal	Principal Investigator's application missing some documents required before acceptance	-Principal Investigator failing to submit all the required documents before acceptance -Failure to use SERU Initial submission Checklist	Training all Principal Investigators about the documents required for the submission of an Initial application

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunity
Submission for Initial Review of a Proposal	Training all Principal Investigators about the documents required for the submission of an Initial application	Organizing trainings for KEMRI and non KEMRI principal investigators to train the principal investigators about the requirements for successful submission of initial applications.

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

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 45 CFR 46 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.402(b)

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

13. ANNEXES

13.1 KEMRI SERU proposal format
13.2 SERU proposal submission form
13.3 Checklist for initial proposal submissions
13.4 Process flow chart

KENYA MEDICAL RESEARCH INSTITUTE

ANNEX 1: AUDIT/ ASSESSMENT FINDINGS SHEET

Appendix 1: KEMRI SERU proposal format

SERU GUIDELINES FOR WRITIN G PROJECT PROPOSALS

1. TITLE OF THE PROJECT: This should be concise and not longer than 30 words.

2. INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS: Non-KEMRI

Investigators should include their curriculum vitae.

3. ABSTRACT: It should provide a concise summary of the background, justification, objective, work planned, nature of results expected, and their significance. This should be structured as one paragraph in NOT MORE THAN 200 WORDS.

4. INTRODUCTION/BACKGROUND: This should be a historical and/or scientific background to the project proposal with literature citations. The literature cited should be listed at the end of the proposal document with the full names of the authors, the title of the publication, the journal/book, the year, volume, beginning and end pages of the article. (THIS SECTION SHOULD NOT EXCEED ONE A4 SIZE PAGE USING 12 PTS TIME NEW ROMAN FONT OR SIMILAR)

5. JUSTIFICATION FOR THE STUDY: This section should give a short justification of the significance of the proposed research, emphasizing how the results will provide new knowledge in the particular field, and why it will be important for national or international development.

(NOT MORE THAN HALF PAGE OF A4 SIZE SINGLE SPACING)

6. STATE THE NULL HYPOTHESIS: Where applicable.

7. (a) GENERAL OBJECTIVES: The main aim should be given clearly. (NOT MORE THAN TWO SENTENCES)

(B) SPECIFIC OBJECTIVES: This section must clearly and unambiguously state the objective(s) of the project. These must be achievable objectives and not statements of the methods to be carried out. The objectives should be written in short concise sentences, and each not consisting of more than two sentences.

(NOT MORE THAN FOUR SPECIFIC OBJECTIVES SHOULD BE GIVEN)

8. DESIGNS AND METHODOLOGY: (a) Study site (Geographical) (b)Study populations

(i) Criteria for inclusion of subjects

(ii) Criteria for exclusion of subjects

(iii)Rationale for animal use and justification for animal species chosen.

(c) Sampling

i. Sample size determination

ii. Sampling procedure

(d) Procedures

(i) Description of the type of data to be collected and collection procedures to be followed.

(ii) Provisions for data verification and validation in the field and laboratory (where applicable).

The structure of this section will be determined by the specific nature of

the study. If it is a clinical study, it should specify such things as study site, patient selection, inclusion and exclusion criteria, summary of the procedures to be used, etc. If it is laboratory and/or field study, it should specify the study site, materials, procedures to be used preferably in bullet form, etc. Where appropriate, calculation of the subject/patient population should be shown. The instruments to be used in surveys, clinical studies, questionnaires, should be appropriately mentioned in the text and copies of such instruments should be attached to the proposal document in the form of Appendices. Similarly, the INFORMED CONSENT FORMS AND EXPLANATIONS should be attached as Appendices.

(THIS SECTION SHOULD NOT EXCEED ONE A4 PAGE SINGLE SPACING USING TIMES NEW ROMAN 12 PTS OR SIMILAR).

9. DATA MANAGEMENT: (a) Data Storage.

i. Provision for database management incorporating how data will be stored before and after analysis.

ii. Description of devices to be used for storage, i.e. type of computer, software to be used in data entry, checking and management.

(b) Data Management (where applicable)

Data Analysis – The statistical techniques to be applied in the analysis to meet the requirements of each of the specific objectives and hypotheses to be tested. This section should concisely describe how the data obtained will be processed, calculated or computed. If a computerized method is to be used, it should specify which software(s) will be used and HOW it will be used. Such statements like “The results will be entered in a computer” without any further explanation will not be accepted. Where results will be processed in the form of tables, a short form of such tables should be given with the headings.(THIS SECTION SHOULD NOT BE MORE THAN HALF OF A4 PAGE SINGLE SPACING)

10. TIME FRAME/DURATION OF THE PROJECT: (a) Pilot study (where applicable)

(b) Definitive study

(c) Data analysis

(d) Report preparation

The total period planned for the project should be stated in months or years, followed by a breakdown of the stages implementation. (NOT MORE THAN HALF A PAGE).

11. ETHICAL CONSIDERATIONS (a) Human Subjects

In all investigations involving human subjects, the following guidelines should be observed:

i "First, do no harm."

ii. Direct benefit to study subjects or community should exist.

iii. Informed consent by subjects and/or community leaders including possible benefits, risks and inconveniences (the protocol should be accompanied by consent-seeking information sheet and informed consent form). See Appendix 1.

iv. Indicate the method of maintaining confidentiality of information obtained during the study.

v. In case of new drugs and/or procedures to be used on human subjects, any possible side effects, untoward reactions and results of previous use even in animals should be stated.

(b) Animal Subjects.

In all investigations involving animals, the following guidelines should be observed:

i. Methods to minimize pain and distress must be specified:

ii. If applicable, a strong justification must be made for not using proper drugs to alleviate pain and distress;

iii If applicable, the method of euthanasia should be specified.

12. EXPECTED APPLICATION OF THE RESULTS: This section should summarize briefly the importance of the expected results and their potential use

or application. (NOT MORE THAN HALF A PAGE)

13. REFERENCES

(a) In the text, use numbering citation method.

(b) In the References page, use the following citation system:

1 Adungo, NI, Mahadevan S, Mulaya NL, Situbi AP and Githure JI: Comparative determination of plasmodium falciparum sporozoite rates in Afrotropical Anopheles from Kenya by dissection and ELISA.

Annals of Tropical Medicine and Hygiene 1991:85:387-394.

2. Okong'o-Odera EA, Abok K, Wamachi A, Mumo J and Koech DK.

Analysis of diagnostic potential of Leishmania donovani antigens.

In: Proceedings of the 12th Annual Medical Scientific Conference, 4-

8 February 1991, Nairobi, Kenya. 1992, pp.271-278.

The literature citations should be provided in full detail, preferably using the numbering style, but in any case, each reference cited in the project proposal must be listed giving: the names of the authors, the full title of the publication, the year of publication, the volume if it is a serial or authors and publishers if it is a book, the beginning and end pages of the article.

14. BUDGET: The budget section should be written in three parts:

a. Budget Summary which should list the major components of the budget, e.g. Travel, Staff emoluments, Equipment, etc.

b. Detailed Budget which should give the break down of each of the sub-sections of the budget summary. The total in (a) and (b) should be the same

The item costs should be given in US dollars (a stable currency), but at the end, the total equivalent in Kenyan Shillings at the time of writing the project, should also be given.

(a) Personnel, salaries and benefits disbursement

(b) Patient costs, travel, food and/or supplies

(c) Major equipment itemized; minor aggregated

(d) Supplies

(e) Travel and accommodation i. Local or field travel

ii. International/Local conferences

(f) Transportation, vehicle repairs, insurance, etc

(g) Operating expenses, postage, printing, etc

(h) Animals: acquisition, food, cages, etc.

(i) Consultancy fees

(j) Contingency funds (15% including inflation) (k) Institutional administrative overheads: 15%

15. JUSTIFICATION OF THE BUDGET:

A short paragraph (NOT MORE THAN HALF A PAGE) should give a justification for the items intended for the project and the cost estimates given.

[THE BUDGET SECTION SHOULD NOT BE MORE THAN TWO AND A HALF PAGES]

16. APPENDICES

(a) State the role of each participating investigator

(c) Attach the relevant documents:

- Curriculum vitae of each non-KEMRI investigator
- Case record and data collection forms
- Informed consent advice and forms

ANNEX 2: SERU PROPOSAL SUBMISSION FORM

REQUEST FOR REVIEW OF RESEARCH PROTOCOL BY KEMRI Centres

This form must be attached to every protocol forwarded to KEMRI's Scientific and Ethics Review Unit

Part A (TO BE FILLED FOR EACH NEW PROTOCOL AT SUBMISSION TO THE CENTRE)

Title: _____

Centre: _____

Research Programme (S) _____

Key Performance Area_____

Strategy _____

Millennium Development Goal _____
(Please refer to SERU page at www.kemri.org for programmes/Key Performance Areas/ strategy and MDGs)

Protocol Version number and date: _____

Name of Principal Investigator(s):_____
Contact phone number for Principal Investigator: _____
E-mail address for Principal Investigator: _____

Institutional Affiliation:

_____

Study Implementation County(s): _____

Expected source of funding: _____

Total amount of funds needed: _____

Declaration: I _____(full names)

Being the principal investigator for this study declare that:

(a) If any changes to this protocol or procedure be desired, the changes shall be requested to the Scientific and Ethics Review Unit (SERU and effected only after written approval by the SERU)

(b) The results of this study will not be published, presented in any journal/conference without the written approval of the Director of the Institute.

(c) The following investigators will participate in this study and are bound by (a) and (b) above.

NOTE: THE TABLE BELOW MUST BE FILLED AND SIGNED BY CO-INVESTIGATORS BEFORE REVIEW BY THE CENTRE

Name/ Institution	Telephone	Email contact	Signature

Signature _____ Date _____
(Principal Investigator)

1.1.1.1

1.1.1.2 PART B (TO BE FILLED AFTER CENTRE REVIEW AND APPROVAL)

This protocol	Yes	No
1) Has been reviewed by the Centre's Scientific Committee		

Any other information _____

_____

This protocol was approved by the Scientific Committee of _____

_____ (Centre) on _____ (date)

Name _____ _____ _____
(Secretary, Scientific Committee) Date Signature

Name _____ _____ _____
(Chairman, Scientific Committee) Date Signature

Name _____ _____ _____
(Director of centre) Date Signature

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)

ANNEX 3: SERU CHECKLIST FOR INITIAL PROPOSAL SUBMISSIONS

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 4: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal investigator	Submits new applications for scientific and ethics review to the SERU secretariat	
Centre compliance Officer	Preliminary review	
Centre compliance Officer	Stamps the documents and give the PI completed and stamped SERU proposal submission checklist, either in hard-copy or as a scanned copy via email, as acknowledgement of receipt of the submitted documents to SERU