In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR SERU ACTION TO APPROVE OR DISAPPROVE RESEARCH

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1. PURPOSE

The purpose of this SOP is to describe the process of approving or disapproving research protocols.

2. SCOPE

This is a guide for investigators to understand how SERU arrives at their decision in regard to protocol review.

3. INTRODUCTION

Several decisions can be made by SERU when discussing research protocols, approval, disapproval or deferment of decisions pending further response from Principal Investigators (PIs). This decision making process will be clearly understood by investigators to allow an efficient interphase with the Scientific and Ethics Review Unit (SERU).

4. TERMS & DEFINITIONS

Refer to SERU Glossary

5. OBJECTIVES

To ensure SERU actions to approve or disapprove research are done effectively and efficiently.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda
7.2Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 No. of applications received

9. RESPONSIBILITY AND AUTHORITY

9.1 A summary of the roles listed in the procedure and the responsibilities of each role holder for the procedures detailed in the SOP.

9.2 The details of the responsibilities should be a brief list of the key tasks performed. This section should not be a complete summary of the SOP.

10. DETAILS OF PROCEDURE

10.1 The SERU committee shall review new KEMRI and NON KEMRI research proposals or applications at its next available meeting providing the complete research proposals or applications are received by the SERU Secretariat on or before the closing date.

10.2 The research proposals or applications shall be assessed by all members present at a given SERU committee meeting and by designated reviewers who have provided typed review comments in absentia.

10.3 The SERU committee shall make an ethical evaluation only on complete research proposals or applications.

10.4 Each research proposal or application requiring initial review shall be individually presented, discussed and acted upon at a convened meeting.

10.5 At least three members designated as primary reviewers, will initiate discussions on the research proposal or application, identify any scientific or ethical issues and facilitate the resolution of any issues raised on the proposal or application.

10.6 In the absence of comments from at least two designated reviewers, the Chairperson shall appoint additional reviewers to ensure the review is completed in a timely manner

10.7 Taking cognizance of the prior scientific review, the SERU committee shall provide an assessment of:

10.7.1 The scientific validity of the research question.

10.7.2 The relevance of the proposed study to the health needs of the community under study.

10.7.3 The risks to potential research participants are minimized and are reasonable in relation to anticipated benefits.

10.7.4 The safeguards that are included to protect the rights and welfare of vulnerable research participants.

10.7.5 Whether or not informed consent/assent will be obtained from research participants and adequately documented.

10.7.6 The need for use of identifiable or potentially identifiable information.

10.7.7 The level of access to information in relation to achieving the study's objectives.

10.7.8 The plans for collection, storage and protection of research data and/or biological samples/specimens.

10.7.9 The provisions for compensation of research participants e.g. for their time, transport costs or lost wages.

10.8 For all NON KEMRI research proposals or applications, the SERU will receive and consider the views on the research proposal held by other duly constituted Research Ethics Committees (RECs) or Institutional Review Boards (IRBs).

10.9 Following the deliberations on a given research proposal or application, the SERU committee(s) will make one of the following decisions at the meeting:

10.9.1 Approve application as submitted if all of the following conditions are satisfied:

10.9.1.1 The risks to research participants are reasonable in relation to anticipated benefits.

10.9.1.2 The knowledge that is expected to result from the research of public health or clinical importance and/or of advancement of the field of research.

10.9.1.3 The risks to research participants are minimized.

10.9.1.4 The selection of research participants is equitable.

10.9.1.5 Informed consent/assent will be sought from each prospective research participants or their legally authorized representative and will be adequately documented, unless a waiver has been granted.

10.9.1.6 The research plan provides for monitoring of data collected.

10.9.1.7 There are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of research data.

10.9.1.8 There are adequate safeguards to protect the rights and welfare of research participants who are vulnerable to coercion or undue influence, where appropriate.

10.9.2 Defer making a decision on the research proposal or application until the reasons for the deferment have been addressed.

10.9.2.1 If minor revisions in the submitted documents are required or a missing document of minor importance is to be obtained, SERU may delegate the chairperson or the head of SERU to approve the project on behalf of SERU. The decision will be ratified in the next full EC meeting

10.9.3 Defer making a decision until specialist advice or opinion has been sought and received, where applicable.

10.9.4 Not recommend ethical clearance if any of the following conditions apply:

10.9.4.1 The study design will mount excessive risks to research participants; or

10.9.4.2 The study design is flawed and will not yield generalizable knowledge of scientific merit;

10.9.4.3 The value of the study results will be negligible. Thus, even though the risks may be minimal and the potential benefit almost zero, the overall risk/benefit ratio would be considered unacceptable; or

10.9.4.4 The study presents significant risk and asks a question that has been answered in earlier research; or

10.9.4.5 There is insufficient safety data on a given investigational product or device to warrant testing in any living individual.

10.10 In case of disagreement between SERU and the investigators of a project under review with regard to requested revisions or a decision to disapprove the project, SERU will provide the opportunity of rebuttal for the investigators, either in writing, or by appearing at a meeting of the SERU committee that made the decision, to defend their cases.

10.11 Under no circumstances will any subject be admitted to the trial/study before SERU issues its written approval/favorable opinion of the trial.

10.12 The SERU committee(s) may at its discretion appoint an ad hoc sub-committee of three (3) persons to undertake further review of a disapproved application prior to communicating to the PI.

10.13 The members of the independent sub-committee shall include at least two (2) experts in the field of research presented by the research proposal or application including one with extensive training in health research ethics, Good Clinical Practice (GCP) and/or experience in human or animal research protections. The ad hoc sub-committee shall be provided with all documents pertaining to the particular application that had been reviewed by the SERU. The review report obtained from the sub-committee shall be used in making a final decision on the proposed research study.

10.14 The SERU committee(s) shall reach a decision on the ethical suitability and feasibility of a given research proposal or application by consensus.

10.15 The SERU committee Chairperson (s) shall ensure that a decision is made on every application considered.

10.16 Where unanimous decisions cannot be reached, the SERU committee(s) shall request for the provision of further information or clarification of any issue(s) by the PI or applicant, or invite the PI/applicant to attend the next convened SERU meeting. The requests for further information or clarification may include modification of the

provisions of the application or any of the supporting documents such as the Informed Consent/Assent Document.

10.17 The SERU committee may delegate to the SERU Secretariat the authority to approve research proposals or applications administratively, in between meetings, if the requested clarification of information, the provision of further information, or incorporation of the requested change is satisfactory. The authority to issue any administrative approval shall be assigned by the convened SERU committee.

10.18 The Head, SERU or the Secretariat shall grant approval to an application previously discussed at a convened SERU committee meeting, when in compliance with the requirements of the SERU committee(s), within six (6) working days of receipt of a satisfactory response from an investigator or applicant.

10.19 The Head, SERU/the Secretariat shall report all approvals that have been granted at the next convened SERU meeting and the update shall be recorded in the minutes.

10.20 Any research proposal or application under SERU review shall remain on the agenda for no more than ninety (90) days i.e. three (3) consecutive scheduled SERU committee (s) meetings.

10.21 Following approval of a study for a term of twelve (12) months, the PI shall be advised to submit an annual study report (Appendix A: Sample Annual or Status Report) 4 weeks or six (6) weeks prior to the date of expiry for observational studies and clinical trials respectively and no later than the deadline for the SERU committee meeting preceding the twelve month anniversary of the date of approval

11. REFERENCE DOCUMENTS

8.1 Internal References

None

8.2 External References

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

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

11 RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Approving or Disapproving Research	Loss of funds in case of Disapproval	Failure to protect research participants	Ensure full protection of participants Training

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Approving or Disapproving Research	Trainings on research participants protection Thorough review of documents	Training

12 ANNEXES

12.1SERU process flow chart

ANNEX 1: 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