In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR ALTERNATIVE REVIEW ARRANGEMENT AND AGREEMENTS

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1. PURPOSE

This SOP describes the processes involved in alternative arrangements and agreements that are necessary to review and approve clinical research protocols for implementation in Kenya.

2. SCOPE

This SOP explains when alternative review arrangements may be employed and how to use the arrangement effectively and efficiently.

3. INTRODUCTION

Review of multi-country/multi-site studies can be duplicative, inefficient, and costly, is outmoded. Alternative review arrangements/agreements such as having a central institutional review board (CIRB) can help address this issue and make the review process more robust and efficient.

4. TERMS & DEFINITIONS

4.1 Affiliated Institutions: Affiliated institutions have a Memorandum of Understanding with the KEMRI SERU as the Institutional Review Board (IRB) of record. The KEMRI SERU has oversight over research conducted at affiliated institutions. A list of affiliated institutions is posted on the IRB web site.

4.2 Cooperative Research Projects: Cooperative research projects involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable regulations.

4.3 External Institution: The KEMRI SERU defines an external institution as:

4.3.1 Engaged in research;

4.3.2 Does not have a Memorandum of Understanding with the KEMRI SERU and;

4.3.3 Is not part of the KEMRI Centres

4.4 Unaffiliated Investigator: An investigator who is not a member of a KEMRI affiliated institution. For a complete description of who can be a principal investigator at KEMRI, see the KEMRI website.

4.5 F acilitated **Review**: A facilitated review is the process an IRB uses when determining whether to accept the review conducted by another IRB (e.g. CIRB). A facilitated

review is not a convened board review and does not issue approval. Rather, a facilitated review accepts and relies on the approval issued by another IRB.

4.6 IRB of record: This is an IRB that assumes IRB responsibilities for another institution. A reliance agreement or Memorandum of Understanding is required designating this relationship.

4.7 Reliance agreement/IRB authorization agreement: A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Such agreements typically cover a designated protocol or protocols. If the authorization agreement covers an entire research program, it is referred to as a memorandum of understanding (MOU). The agreement clearly identifies the IRB of

5. OBJECTIVES

To ensure alternative review arrangement and agreement procedures are performed 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 Responsibilities of the local institution:

9.1.1 Addressing issues to be assessed prior to IRB review, such as conflict of interest, radiation safety, and biosafety reviews

9.1.2 Ensuring ICFs include local information and adaptations

9.1.3 Receiving and managing reports of local adverse events (AEs)

9.1.4 Handling subject complaints and allegations

9.1.5 Monitoring the conduct of the approved trial, including assuring that applicable regulations are followed

9.1.6 Conducting Quality Assurance/Quality

9.1.7 Improvement (QA/ QI) activities (self-audit)

9.1.8 Assuring investigators and research staff are trained and competent

9.1.9 Ensuring the trial is appropriate for the patient population in the institution

9.2 Responsibilities of the central review body:

9.2.1 Review of the study design

9.2.2 Review of the ethics of the study

9.2.3 Ensure the quality of the consent template (e.g., readability, translations, level of language)

9.2.4 Perform aggregate analysis of all AEs, including reports from the DSMB to the IRB

9.2.5 Confirm the competency of the investigator

10. DETAILS OF PROCEDURE

10.1 Policy - The KEMRI SERU with the approval of the Director KEMRI, may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-Wide Assurance Agreements (FWA).

10.2 KEMRI SERU Review for External Institutions:

10.2.1 The KEMRI SERU may review and approve a research project conducted at an external institution as a non-KEMRI research project. This decision is made on a case-by- case basis by the KEMRI SERU (with the approval of the Director KEMRI) upon submission of a proposal by a P.I from the External Institution.

10.2.2 In order for the KEMRI SERU to consider becoming the Institutional Review Board (IRB) of record for a research project conducted at an External Institution, all requirements must be met as outlined on the IRB website.

10.2.3 The External Institution must enter into a Reliance Agreement or an IRB Authorization Agreement with the KEMRI SERU and provide any requisite documents to the KEMRI SERU.

10.2.4 Agreements will specify the type(s) of research or the individual research project conducted under the agreement and outlines the duties and responsibilities of the KEMRI SERU and the External Institution/Investigator.

10.2.5 Copies of any agreements and any accompanying documentation must be retained by both the KEMRI SERU and the External Institution.

10.2.6 The KEMRI SERU files such agreements in the Head SERU's office as well as a copy of the agreement with the research proposal.

10.3 Reviews by another IRB of Record for Research Conducted at the KEMRI (Facilitated Review by the KEMRI):

10.4 If the KEMRI SERU relies on another IRB (i.e. use of a central IRB for multi-site/multi-country or cooperative group clinical trials) for research conducted at the KEMRI:

10.4.1 The KEMRI SERU retains ultimate responsibility for maintaining a human research protection plan including, but not limited to:

10.4.1.1 Safeguarding the rights and welfare of human research participants within the local context. The KEMRI SERU retains the responsibility to maintain oversight for local unanticipated problems involving risks to participants or others and non-compliance. The KEMRI SERU retains the authority to conduct audits to ensure compliance.

10.4.1.2 Conduct conflict of interest review for KEMRI investigators.

10.4.1.3 Educating members of the KEMRI's research community to establish and maintain compliance of federal regulations and institutional policies relevant to human research participants.

10.4.2 Implementing appropriate oversight mechanisms, within the local context, to ensure compliance with the determinations of the reviewing IRB Respective responsibilities of the KEMRI SERU and the IRB of record must be put in writing. The agreement will document, at a minimum, the following items

10.4.2.1 Role and responsibility of the IRB of record;

10.4.2.2 The authority of the IRB of record to oversee the study;

10.4.2.3 The responsibility of the IRB of record for oversight and continuing review

10.4.3 The KEMRI SERU will modify the current federal wide assurance by adding the IRB which will be the IRB of record for research conducted at the KEMRI.

10.4.4 The Head SERU/ Institutional Official and SERU Committee Chair will evaluate the adequacy of the proposed IRB in light of the scope and purpose of the research, as well as the participant populations likely be to involved, the appropriateness of initial and continuing review in light of probable risks, and the size and complexity of the institution.

10.4.5 The proposed IRB is evaluated to ensure policies and procedures are in place which provide arrangements for communication with participating sites in order to provide sufficient knowledge of the conditions surrounding the conduct of the research, and to ensure that risks to subjects are minimized and assure that the IRB of record will be made aware of unexpected problems in a timely manner.

10.4.6 The Head SERU, IRB Chair and Director KEMRI make the final decision of whether to enter into an agreement allowing for another IRB to review research conducted at the KEMRI.

10.4.7 Copies of any agreements must be retained by both the KEMRI SERU and the External Institution. The Head SERU or designee is responsible for maintaining copies of such agreements.

10.5 Review by another IRB of Record for a Single-Project:

10.5.1 If a research project is conducted entirely at an External Institution it may still require KEMRI SERU approval (e.g. KEMRI scientist/staff is an investigator, etc.).

10.5.2 If the research is no more than minimal risk and there is an IRB at the External institution, the KEMRI SERU (with the approval of the Institutional Official) may allow the External Institution's IRB to be the IRB of record for the single project. This will be addressed on a case-by-case basis.

10.5.3 KEMRI must enter into an IRB Authorization Agreement with the External Institution in order for this to occur.

10.5.4 Copies of any agreements must be retained by both the KEMRI SERU and the External Institution. The Head SERU or designee is responsible for maintaining copies of such agreements.

10.6 Research Activities Conducted at KEMRI by Unaffiliated Investigators:

10.6.1 The KEMRI SERU will acknowledge recruitment of subjects for research conducted by an unaffiliated investigator at the KEMRI (or an affiliated institution) when:

10.6.1.1 The KEMRI SERU does not act as the ethical review board; and

10.6.1.2 Research activities are not conducted at the KEMRI (or an affiliated institution).

10.6.2 The KEMRI SERU will defer the approval process of recruitment of subjects only to the specific Institutional or departmental head/authority.

10.6.3 If the unaffiliated investigator wishes to conduct recruitment AND research activities at KEMRI (or an affiliated institution), the KEMRI SERU requires that the unaffiliated investigator obtain an affiliated faculty sponsor at the KEMRI who will act as the principal investigator at the KEMRI.

10.6.4 A complete research application for review and approval is required before any recruitment or research activities occur.

11. RISKS AND OPPORTUNITIES

11.1 **Risks**

Process	Risk	Risk source	Mitigation
Alternative review arrangement and agreement	Delay in getting approval of the document	Divergent view, culture and belief of the reviewers especially if it is multicentre	Get documents ready in good time

11.2 **Opportunities**

Process	Opportunities	Action plan to maximise the opportunities
Alternative review arrangement and agreement	Set up internal research regulation	Have the regulation team analyse first the documents before submitting for IRB approval

12. REFERENCE DOCUMENTS

12.1 Internal References

None

12.2 External References

https://irb.utah.edu/_pdf/IRB%20SOP%20409%20version%20L0612%202.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4267852/

13. ANNEXES

12.3 Annex 1 - SERU Institutional Review Board (IRB) Authorization/Reliance Agreement

12.4 Annex 2 – SERU process flow chart

ANNEX I: SAMPLE INSTITUTIONAL REVIEW BOARD (IRB) AUTHORIZATION/RELIANCE AGREEMENT

Sample text for an Institution with a Federal wide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).

Institution or Organization Providing IRB Review:

Name (Institution/Organization A): _____

IRB Registration #: _____

Federal wide Assurance(FWA)#, if any: _____

Institution Relying on the Designated IRB (Institution B):

Name: _____

FWA#: _____

The Officials signing below agree that _____(name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one):

(___) This agreement applies to all human participants research covered by Institution B's FWA.

(___) This agreement is limited to the following specific protocol(s):

Name of Research Project: _____

Name of Principal Investigator: _____

Sponsor or Funding Agency: _____

Award Number, if any: _____

(___) Other (describe): _____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

_____

Date: _____

Print Full Name: _____

Institutional Title: _____

Signature of Signatory Official (Institution B):

_____

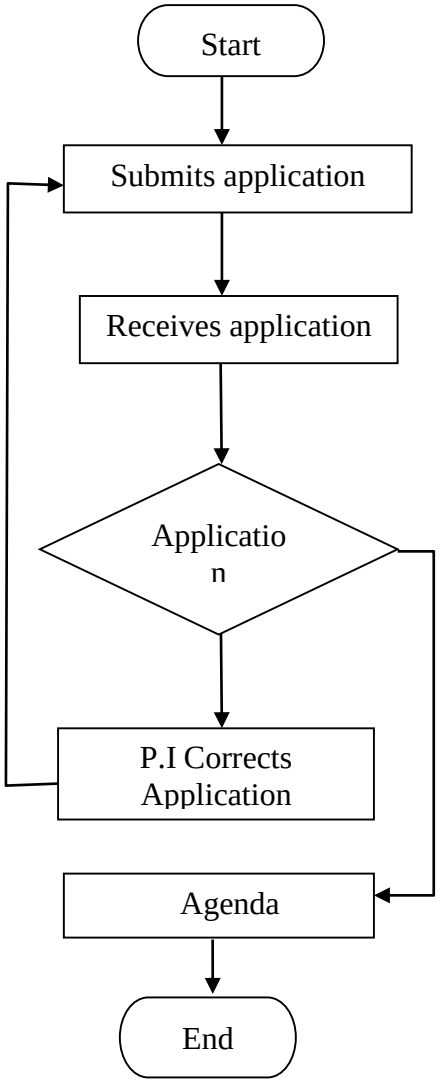
Date: _____

Print Full Name: _____

Institutional Title: _____

Content adapted from Office for Human Research Protections

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	