

**Appendix 4: TOM MBOYA UNIVERSITY-SERC REVIEW EVALUATION FORM**

**INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)  
TOM MBOYA UNIVERSITY - KENYA  
RESEARCH ETHICS REVIEW EVALUATION FORM**

**Application No: year/IERC- ....**

**Title:** \_\_\_\_\_

		Yes	No	N/A	Comments
	<b>Is all the documentation provided?</b>				
	<b>Scientific importance and validity</b>				
1	Will the study lead to a) improvements in human health and wellbeing? b) Increase knowledge?				
2	a) If the study is a replication of a previous study, b) If YES above, Is it justified (mention in comments)?				
3	If this is an intervention study, can it be practically implemented?				
4	Is there provision for dissemination of results of the research?				
5	a) Has the research protocol been approved by a Scientific Committee/ body? b) Has the research proposal been approved by an accredited Ethics body/IERC/IRB?				
6	Are the objectives stated clearly?				
7	Is the study design appropriate in relation to the objectives?				
8	Is the study designed using accepted principles, methods and practices?				
9	Is there a plausible data analysis plan?				
10	Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?				

		Yes	No	N/A	Comments
11	Are the investigators qualifications, competence and experience appropriate to conduct the study?				
12	Are the facilities at the site adequate to support the study?				
13	Is the manner in which the results of research will be reported and published ethical?				
	<b>Assessment of Risks/Benefits</b>				
1	Is the involvement of human participants necessary to obtain the necessary information?				
2	Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
3	Are there any plans to withdraw or withhold standard of care for the purpose of research and such actions if any justified?				
4	Is the proposed standard of care in keeping with best local practices?				
5	Is the medical and psychological support for the participants adequate?				
6	Does the study site have adequate support staff, facilities and required emergency procedures?				
7	Is there provision for compensation for participants who sustain research related injuries?				
8	Have adequate provisions been made for dealing with and reporting adverse events?				
9	Have adequate provisions been made for safety monitoring and termination of the research project?				
10	Is there a possibility of an intervention being available to the population if found effective?				
	<b>Respect for the dignity of the research participants</b>				
	<b><i>Informed consent</i></b>				
1	Is the process for obtaining informed consent appropriate?				
2	Do participants have the capacity to consent?				
3	Is the justification for the intention to include individuals who cannot consent adequate?				
4	Are the arrangements for obtaining surrogate consent or assent for such individuals appropriate?				

		Yes	No	N/A	Comments
5	Will refusal to participate be respected?				
6	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable? Include an assessment of language level with the proposal e.g. FOG index				
7	Do you approve the compensation offered?				
8	Is the consent given voluntarily?				
9	Will fresh informed consent be obtained if the procedures are changed during the research?				
10	Is there an opportunity for the participant to ask questions regarding the research?				
	<b>Confidentiality</b>				
1	Is the privacy of the research participant safeguarded?				
2	Are data/ biological specimen storage and disposal procedures adequate to protect participant confidentiality?				
	<b>Rights of the participants</b>				
1	Is the participant's right to unconditionally withdraw from the research at any time safeguarded?				
2	Is there provision for the participants to ask questions and register complaint?				
3	Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
4	Is there provision for the subjects to be informed of results of research?				
5	Is there provision to make the study product available to the participants following research?				
	<b>Fair participant selection</b>				
1	Has the study population been determined, primarily, based on the scientific goals of the study?				
2	Is the selection of participants appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				

		Yes	No	N/A	Comments
3	Does the selection of participants stigmatize any group?				
4	Does selection of subjects favour any group?				
5	Is the initial contact and recruitment appropriate?				
6	Is the research conducted on vulnerable individuals or groups? E.g. children, prisoners, pregnant women, handicapped, mentally disabled persons				
7	Is the research externally sponsored?				
8	Is the research a community research?				
9	Is the research a clinical trial?				
	<b>Responsibilities of the researcher</b>				
1	Has the researcher followed any applicable legal regulations or other guidelines?				
2	Has the researcher obtained permission from the relevant authorities?				
3	Are there any other ethical / legal/ social /financial issues in the study?				
	<b>Vulnerable group e.g.</b> children, prisoners, pregnant women, handicapped, mentally disabled persons				
1	Can the research be equally well carried out in another, less vulnerable, group?				
2	Will the study result in new knowledge relevant to the health needs of this population?				
3	Is the procedure for obtaining proxy/surrogate consent adequate?				
4	Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
5	Does the study benefit outweigh the risk?				
6	Will the benefit of the research be made available to this group?				
	<b>Externally sponsored research</b>				
1	Is there a local co –investigator?				
2	Has the research project been approved by a ERC/ IRB in the sponsoring country?				
3	Is the justification for the research to be carried out in Kenya and not in the sponsoring country/institution adequate?				

		Yes	No	N/A	Comments
4	Are the post-research benefits to Kenya acceptable?				
5	Are relevant local laws/ regulations/guidelines of each country adhered to?				
6	Is the research responsive to cultural/social differences?				
7	Are participants receiving the best current treatment as part of the protocol?				
8	Are the provisions for intellectual property sharing fair?				
9	If the data/biological materials are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights? Ref to Material Transfer Agreement				
10	Is there provision for results of research to be conveyed to relevant authorities in AKU, EA?				
11	Are there any conflicts of interest? If yes, provide details?				
12	Is there a written agreement between the collaborators?				
<b>Community based research</b>					
1	Is the study relevant to the needs of the community?				
2	Is the study culturally acceptable?				
3	Does the research study in any way stigmatize the participants?				
4	Before commencement of the study, have the concerned community leaders and other key stakeholder been consulted to consent to design of the study?				
5	Is community consent obtained?				
6	Is individual consent obtained?				
7	Is the privacy of the participants safeguarded?				
8	If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?				
9	Will the intervention or product developed or knowledge generated be made available and affordable for the benefit of the population?				
10	Does the research contribute to capacity building of the community?				

		Yes	No	N/A	Comments
11	Will the results of the research be made available to the concerned community leaders and other key stakeholders in the community?				
12	Are any conflicts of interest resolved?				
<b>Clinical trials</b>					
1	If it is a multicentre trial, are all centres following the same protocol?				
2	Is the clinical trial registered with a clinical trials registry?				
3	Have adequate animal toxicity and teratogenicity trials been carried out?				
4	Is their sufficient justification for using a placebo control arm?				
5	Does the control group receive the standard therapy?				
6	Are all subject participants treated equally?				
7	Is the procedure for dealing with adverse events adequate?				
8	Is the procedure for reporting adverse events adequate?				
9	Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?				
10	Are the criteria for termination of the trial detailed?				
11	Is there provision for insurance of trial participants?				

**Summary of comments**

**Risk Level:** High  Medium  Low

**Recommendation:** Approve  Resubmit (please state conditions)  Reject **R**