# Appendix 4: IERC Review Evaluation Form

**INSTITUTIONAL ETHICS REVIEW COMMITTEE (IERC)**

**THE AGA KHAN UNIVERSITY - KENYA**

**RESEARCH ETHICS REVIEW EVALUATION FORM**

**Application No: year/IERC- ….**

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



|  |  | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
|  | **Is all the documentation provided?** |  |  |  |  |
|  | **Scientific importance and validity** |  |  |  |  |
| 1 | Will the study lead to   1. improvements in human   health and wellbeing?   1. Increase knowledge? |  |  |  |  |
| 2 | 1. If the study is a replication of a previous   study,   1. 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 | 1. Has the research protocol been approved by a   Scientific Committee/ body?   1. 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? |  |  |  |  |
| 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? |  |  |  |  |
|  | **Assessment of Risks/Benefits** |  |  |  |  |
| 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? |  |  |  |  |
|  | **Respect for the dignity of the research participants** |  |  |  |  |
|  | ***Informed consent*** |  |  |  |  |
| 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? |  |  |  |  |
| 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? |  |  |  |  |
|  | ***Confidentiality*** |  |  |  |  |
| 1 | Is the privacy of the research participant safeguarded? |  |  |  |  |
| 2 | Are data/ biological specimen storage and disposal procedures adequate to protect participant confidentiality? |  |  |  |  |
|  | ***Rights of the participants*** |  |  |  |  |
| 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? |  |  |  |  |
|  | **Fair participant selection** |  |  |  |  |
| 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? |  |  |  |  |
| 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? |  |  |  |  |
|  | **Responsibilities of the researcher** |  |  |  |  |
| 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? |  |  |  |  |
|  | **Vulnerable group e.g.** 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? |  |  |  |  |
|  | **Externally sponsored research** |  |  |  |  |
| 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? |  |  |  |  |
| 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? |  |  |  |  |
|  | **Community based research** |  |  |  |  |
| 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? |  |  |  |  |
| 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? |  |  |  |  |
|  | **Clinical trials** |  |  |  |  |
| 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 MediumLow

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