

HUBERT KAIRUKI MEMORIAL UNIVERSITY
 INSTITUTIONAL RESEARCH ETHICS COMMITTEE

FORM HK/IREC 04 - 01: APPLICATION ASSESSMENT FORM

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|----------------------------------|---|-----------|
| Title of protocol: | Protocol No: | Date..... |
| Principal investigator: | | |
| Co-Investigators: | 1. 2. 3. 4. 5. 6. 7. | |
| Total no. of study participants: | | |
| Funding agency: | | |
| Review status: | Initial [] Resubmission [] Amendment [] Termination [] | |
| Principal reviewer(s) | 1 2 3 4 5 | |
| Project status: | Single site [] Multiple study site [] | |
| The study in brief: | | |
| Study design: | Simple randomized [] Stratified randomized [] Single blind [] Double blind [] Triple blind [] Placebo controlled [] Compare with standard treatment [] Cross-over [] Parallel [] | |
| Objectives of the study: | 1 2 3 4 5 6 7 8 9 10 | |
| Methodology: | | |

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| Objectives of the study: | Clear <input type="checkbox"/> Not clear <input type="checkbox"/> What should be improved |
| Need for human participants | Yes <input type="checkbox"/> No <input type="checkbox"/> Comment: |
| Methodology: | Clear <input type="checkbox"/> Not clear <input type="checkbox"/> What should be improved? |
| Background information: | Clear <input type="checkbox"/> Not clear <input type="checkbox"/> Comment: |
| Risk/benefit ratio assessment: | Fair <input type="checkbox"/> Unfair <input type="checkbox"/> Comment: |
| Sampling frame size: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |
| Sample calculation: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |
| Sampling method: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |
| Sample size: | Adequate <input type="checkbox"/> Not adequate <input type="checkbox"/> Comment: |
| Inclusion criteria: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |
| Exclusion criteria: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |
| Withdrawal criteria: | Okay <input type="checkbox"/> Not okay <input type="checkbox"/> Comment: |

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| Involvement of vulnerable participants: | Yes [] No [] Comment: |
| Procedures of recruitment of participants: | Okay [] Not okay [] Comment: |
| Control arms if applicable: | Yes [] No [] Comment: |
| CV of investigators: | Qualified [] Not qualified [] Comment: |
| Disclosure of potential conflicts: | Yes [] No [] Comment: |
| Facilities and infrastructure of participating sites (institutions): | Appropriate [] Adequate [] Not appropriate/adequate [] Comment: |
| Community consultation: | Yes [] No [] Comment: |
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| Involvement of local researchers and institutions in protocol design, data collection, analysis and publication of results: | Yes [] No [] Comment: |
| Contribution to development of local human and physical institutional infrastructure/capacity building for research: | Yes [] No [] Comment: |
| Availability of study results to local community: | Yes [] No [] Comment: |
| Benefits of study to local community: | Yes [] No [] Comment: |

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| Voluntary, non-coercive (inducement) Recruitment/participation: | Yes [] No [] Comment: |
| Procedures of obtaining informed consent | Appropriate [] Not appropriate [] Comment: |
| Contents of the informed consent: | Adequate/clear [] Not adequate/clear [] Comment: |
| Language of the informed consent document | Appropriate/clear [] Not appropriate/clear [] Comment: |
| Contact persons for participants | Appropriate/clear [] Not appropriate/clear [] Comment: |
| Privacy and confidentiality | Yes [] No [] Comment: |
| Provision for medical/psychosocial support | Yes [] No [] Comment: |
| Provision for treatment for study related injuries: | Yes [] No [] Comment: |
| Provision for compensation | Yes [] No [] Comment: |
| Statistics to be used: | Appropriate/clear [] Not appropriate/clear [] Comment: |
| Plans for dissemination of results | Appropriate/clear [] Not appropriate/clear [] Comment: |
| Budget | Justifiable/justified [] Not Justifiable/justified |

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| | <input type="checkbox"/> Comment: |
| Decision | <input type="checkbox"/> Approved <input type="checkbox"/> Approved with recommendations <input type="checkbox"/> Resubmit revised version <input type="checkbox"/> Disapproved <input type="checkbox"/> Comments: |
| Signature..... | Date |