

KAIRUKI UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

FORM KU/IREC 04 - 01: APPLICATION ASSESSMENT FORM

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:			

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

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:
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:

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 [] Comment:
Decision:	Approved [] Approved with recommendations [] Resubmit revised version [] Disapproved [] Comment:
Signature..... Date	