Ethics Review Evaluation Form - Human

for official use

Application No:

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy maker or statistical expert?				
If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person.				
If NOT,				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Is the study designed using accepted principles, methods and practices?				
10. Is there a plausible data analysis plan?				
11. Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?				
12. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
13. Are the facilities at the site adequate to support the study?				
14. 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. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. How safe is the intervention to be used in the research?				

	Yes	No	NA	Comments
4. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
5. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
6. Is the standard of care the best available locally?				
7. Is the medical and psychological support for the participants adequate?				
8. Is the site including support staff, facilities and emergency procedures adequate?				
9. Is there provision for compensation for participants who sustain injuries?				
10. Have adequate provisions been made for dealing with and reporting adverse effects?				
11. Have adequate provisions been made for safety monitoring and termination of the research project?				
12. 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. Are the participants competent?				
3. Is the justification for the intention to include individuals who cannot consent adequate?				
4. Are the arrangements for obtaining proxy consent for such individuals appropriate?				
5. Will dissent be respected?				
6. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
7. Do you approve the incentives offered?				
8. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
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. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				

	Yes	No	NA	Comments
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
Rights of the participants				
1. Is the participant's right to unconditionally withdraw from the research at anytime 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 clinical 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 (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2. Is the selection of participants (inclusion and exclusion criteria) 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?				
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. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher followed any applicable legal regulations or other guidelines?				
3. Has the researcher obtained permission from the relevant authorities?				
4. Are there any conflicts of interest, including payments and other rewards?				

	Yes	No	NA	Comments
5. Are there any other ethical / legal/ social /financial issues in the study?				
Vulnerable group				
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) consent adequate?				
4. Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
5. Is there a favourable risk benefit ratio?				
6. Is the medical and psychological support adequate?				
7. Will the benefit of the research be made reasonably available to this group?				
Externally sponsored research				
1. Is there a local collaborator?				
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 Sri Lanka and not in the sponsoring country adequate?				
4. Is the research relevant to Sri Lanka?				
5. Are the post-research benefits to the country acceptable?				
6. Are relevant local laws/ regulations/ guidelines of each country adhered to?				
7. Is the research responsive to cultural/social differences?				
8. Are participants receiving the best current treatment as part of the protocol?				
9. Is the ancillary care provided adequate?				
10. Are the provisions for continuity of care adequate?				
11. Are the provisions for intellectual property sharing fair?				
12. If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?				
13. Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?				
14. Are any conflicts of interest resolved?				
15. Is there a written agreement between the collaborators?				

	Yes	No	NA	Comments
Community based research				
1. Is the impact and relevance of the research on the community in which it is to be carried out acceptable?				
2. Has the concerned community been consulted during the design of the study?				
3. Is community consent obtained?				
4. Is individual consent obtained?				
5. Is the privacy of the participants safeguarded?				
6. If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?				
7. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?				
8. Does the research contribute to capacity building of the community?				
9. Will the results of the research be made available to the concerned community?				
10. 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 teratogenecity trials been carried out?				
4. Is their sufficient justification for using a 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?				

Final Assessment:

	Pass	Concerns
Collaborative partnership	☐	
Scientific value	☐	
Scientific Validity	☐	
Fair Selection of Humans/animals	☐	
Favourable Risk / Benefit ratio	☐	
Informed Consent of owners	☐	
Respect for Humans enrolled for the study	☐	

Additional Comments:

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Recommendation: Approve ☐ Reject ☐

Conditional Approval (Please state the conditions) ☐

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Name of the Reviewer: ……

Signature: ……

Date: ……