

F-1-39-6
APPENDIX 7: MIRERC
Amendment Request Form

*

| Section 1 | | | |
|--|---------------------------|--|--|
| Title of Research Study: | Click here to enter text. | | |
| Principal Investigator: | Click here to enter text. | Study Registration Number: | xxsxxxx |
| Supervisor: (If applicable) | Click here to enter text. | MUST Position: | [i.e.: Staff, Graduate Student, Postdoctoral Fellow] |
| Q1. Please indicate if your School Supervisor has reviewed this completed form and has given their approval for you to submit this form to MIRERC. It is the responsibility of the principal investigator (PI) to ensure that all approvals are in place before this form is submitted. | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable | |
| Q2. Is this study a clinical trial? If no , please skip to Section 2. | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q3. Has the clinical trial registry been updated with respect to this amendment? | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q4. Is Health NACOSTI approval required for this amendment? | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q5. Did the initial protocol require an approval letter from the Kenya National Council for Science, Technology and Innovation (NACOSTI)? If yes , please include a copy of the letter for this amendment or provide the rationale for why this is not required. | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Section 2 | | | |
| Q1. Is your study funded by the Kenya National Research Fund (NRF)?: If yes , please note that review of the amendment may require full MIRERC review unless the research activities present no more than minimal risk to human participants, that may be reviewed through an expedited review procedure. | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q2. Does this study involve the recruitment of human participants? If yes , is recruitment ongoing? | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q3. Does this Amendment require a change in the sample size for this study? | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Q4. Has this study received approval from other institutions or Health Authorities? If yes , please specify (and include relevant documentation): | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |

F-1-39-6
APPENDIX 7: MIRERC
Amendment Request Form

| | |
|---|---|
| <p>Q5. Will the Principal Investigator (PI) be changed on the study?</p> <p>If yes, please provide the name of the new PI and the necessary contact information and submit a completed change of PI form to the MIRERC.</p> <p>Name and contact information of new PI: </p> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>Briefly describe the nature of the proposed change(s) to the study:</p> | |
| <p>[Please provide additional information]</p> | |
| <p>Please briefly explain the reasons why you want to make the proposed changes:</p> | |
| <p>[Please provide additional information]</p> | |
| <p>Section 3</p> | |
| <p>Please check all the boxes that apply to the sections of the original ethics application that you wish to change:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Change of Principal Investigator (PI) <input type="checkbox"/> 'Administrative change' (e.g., changes in granting status, staff personnel, contact person, etc.) <input type="checkbox"/> Recruitment process <input type="checkbox"/> Incentives for participants <input type="checkbox"/> Advertisements /posters <input type="checkbox"/> Letters of invitation for participation <input type="checkbox"/> Study details <input type="checkbox"/> Methods or procedures <input type="checkbox"/> Questionnaires, tests, surveys, etc. <input type="checkbox"/> Procedures to ensure participant confidentiality <input type="checkbox"/> Other (please list): <p>Note: Provide this completed form with all new or revised documents. Highlight all current changes to documents, and include an updated version date and number, when applicable.</p> | |
| <p>Section 4</p> | |
| <p>Q1. Do the proposed changes to the study require any amendment to the consent/assent process?</p> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable |

F-1-39-6
APPENDIX 7: MIRERC
Amendment Request Form

| | |
|---|---|
| <p>If yes, please attach a revised consent/assent form to this application highlighting only the current changes in yellow and updating the version date for the document(s).</p> | |
| <p>Q2. Indicate whether or not the proposed changes will result in any increase in risk for the study participants beyond what was originally anticipated. If yes, please explain below what the increased risks are and why they are necessary.</p> | <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> |
| <p>[Click here to provide description]</p> | |
| <p>Q3. Has your study experienced any Unanticipated Problems according to the definition provided in the Guidance document associated with this form? If yes, please explain in the section below. *Please note that Serious Unanticipated Problems must be reported to the MIRERC in a timely manner using an Unanticipated Problems Form.</p> | <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> |
| <p>[Click here to provide description]</p> | |
| <p>Q4. Have there been any changes in Conflict of Interest? If yes, please explain below. *A Conflict of Interest must be reported using a Conflict of Interest form.</p> | <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> |
| <p>[Click here to provide description]</p> | |