

Knowledge Innovation Excellence

**LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)**

**GENERAL ADMINISTRATIVE GUIDELINES**

**AND**

**STANDARD OPERATING PROCEDURES**

**LUANAR Research Ethics Committee**

**P.O Box 219**

**Lilongwe, Malawi.**

**February 2025**

**LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)**

**LUANAR-REC FORM 004: Request for Amendment/Modification**

**Please complete the following**

|  |  |
| --- | --- |
| **LUANAR-REC REF. Number**(LUANAR-REC will not process requests without this number.) | **Date of Request** |
| **Principal Investigator Name****Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Contact Person** (if other than PI)**Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Title of study** |  |

1. Description of proposed changes: (**Note:** Changes may not be implemented before REC approval and use attachments and additional pages, as needed.
2. Reason for Amendment/Modification (including if and how the risks/benefits have changed).
3. Changes to Consent Form: Are changes required? No \_\_\_\_\_\_\_ Yes \_\_\_\_\_\_\_ (If Yes, then attach new consent form)

**Principal Investigator’s Assurance Statement:**

I understand the RECs policy concerning research involving human and animal participants and I agree to;

1. accept responsibility for the scientific and ethical conduct of this research study,
2. obtain prior approval from the REC before amending or altering the research protocol or implementing changes in the approved consent form,
3. immediately report to REC any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study,
4. train study personnel in the proper conduct of human and animal participant's research,
5. Complete the Continuing Review and Final Report Forms.

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**Signature of Principal Investigator Date**

**Approval of Changes/Modifications by LUANAR-REC**

**Chairperson Recommendation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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LUANAR-REC Office Use only:

Approval

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approved by:

**Chairperson Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_