

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 005: Application for Continuing Review of Research Activity**

**STATEMENT OF POLICY**

It is the policy of LUANAR-REC that in the continuing review of ongoing research, the entire study will be reviewed to ensure the continued protection of the rights and welfare of the research participants. The continuing review process must be no less stringent than the initial review.

The Principal Investigator is responsible for the timely submission of a continuing review application to prevent any lapse in LUANAR-REC approval. REC regulations do not provide for exceptions to the requirement for continuing review. Therefore, failure by the Principal Investigator to ensure the timely review is a serious matter that may lead to suspension or termination of the study. **NO EXTENSIONS CAN BE GRANTED.**

If applying for re-approval for long-term follow-up or data analysis only, complete sections A, C, D, E, F, and H only.

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| 1. **STUDY INFORMATION** | | | | |
| **LUANAR-REC Protocol Number as assigned** |  | **The expiration date of the current approval period** | |  |
| **Project Title** |  | | | |
| **Principal Investigator** |  | | | |
| **Institution** |  | | | |
| **Phone** |  | **Email** |  | |
| **Contact Person**  **(if applicable)** |  | | | |
| **Institution** |  | | | |
| **Phone** |  | **Email** |  | |

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| 1. **PROJECT FUNDING** |  |
| **Funding Sources:** | * + - * 1. **Agency/Company Name** |
| * + - * 1. **Agency/Company Name** |
| * + - * 1. **Agency/Company Name** |

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| 1. **RESEARCH OR PROJECT SITE (S)** |
| **List all performance sites for this study (including names of foreign countries with sites)** |

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| 1. **STATUS OF STUDY (Tick one box)** |
| **Active study**  Recruitment/enrolment continues  Accrual complete, research intervention continues  Long-term follow-up  Data analysis only, data collection complete |

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| 1. **INTERVENTION INFORMATION**   **Intervention**  Survey questionnaire Experimental Protocol Drug    Other, briefly explain.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **PROGRESS REPORT** |
| **1. Enrolment and demographic information: LEAVE NO LINE BLANK**   1. The total number of participants requested in the original LUANAR-REC application   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Number of participants enrolled since the last progress report   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Number of participants enrolled since the start of the study   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please report the number of participants in Malawi in the following categories: (Numbers must add up to point (iii) above. Please check before submitting the form)   1. Currently active in study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   *Note: The number must be equal to the total of the two sub-categories below*     * Follow-up data collection only \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      * Completed intervention \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  1. Withdrawn from study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. Deaths related to study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. Deaths unrelated study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. Lost to follow-up \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2. Adverse Events, Complications, Study Withdrawals:**  In the past approval period, did any subjects suffer an unanticipated or serious adverse event or death? Yes No  **If yes, please attach the Adverse Event Report(s) if adverse events have not already been reported to LUANAR-REC**  **Adverse events/overall risk: If YES, Answer every question.**   * Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to participants? Has anything occurred since the last REC review that may have altered the risk/benefit relationship? Explain. * Did you withdraw any subject(s) from your study because of a problem or complication? Explain. * Did any subject(s) withdraw themselves from your study? Explain. * Did any problems occur in obtaining or documenting informed consent (i.e., problems with subject understanding)? Explain? |
| 1. **Progress Yearly Report:**   **Please attach:** A brief summary of findings (preliminary or final) obtained in the study, a summary of recent literature or relevant information, especially information about risks associated with the study. Begin with a 1 – 2 sentence description of the purpose of the study. **State and explain if there are no findings at this time**. | |
| **G. AMENDMENT/REVISION REQUEST:** Tick YES if an Amendment or Revision is requested and submit it together with Form 004 (Request for Amendment/Modification).  YES NO | |

**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 participants' research,
5. Complete the Continuing Review and Final Report Forms.

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**Signature of Principal Investigator Date**

**THIS SECTION IS FOR LUANAR-REC USE ONLY**

**Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LUANAR-REC Office Use only:

Approval

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

Approved by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Decision:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Chairperson’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_