

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 FORM 003: Checklist for Principal Investigators When Submitting Research Proposals to REC**

**Please make sure you check all the boxes below and attach the completed checklist to the front of your proposal/protocol when submitting.**

**TITLE:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of Principal Investigator:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of Sponsor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Amount of funding:** **USD**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**MK**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Have you submitted this proposal to another Ethics Committee?** **Yes No**

**If submitted, please specify the final reviewer’s decision and if approved, submit a copy of the approval letter with this submission.**

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**Please ensure that the following are included as attachments to your proposal:**

1. Covering letter from Principal Investigator
2. Letter of support from
   1. Head of the Department hosting the research
   2. Other departments co-hosting the research (*if applicable*)
3. One electronic copy of the study proposal and all attachments as specified below

* The proposal/protocol should have the following sections:
  1. Title
  2. Abstract
  3. Introduction/Background
  4. Rational/ justification
  5. Objectives of the study
  6. Literature review
  7. Methodology/ Experimental Design 
     + Type of study, design, and setting
     + Study population (human and/or animals)
     + Study period
     + Sample size
     + Data collection and management
     + Data Analysis

1. Research dissemination strategy
2. Ethical considerations
   * + The adequacy of the Informed Consent Form (in English and local language)
     + Inclusion and Exclusion Criteria of subjects/participants
     + Benefits (direct and indirect) and risks intensity in human and/or animal subject research.
     + How will risks be managed or avoided altogether in human and/or animal subject research?
3. Workplan
4. Itemised budget that includes:
   * + Detailed budget item lines and justification or budget notes for each item
     + A 10% allocation to research compliance and capacity building fee when the study is approved (Not applicable for undergrade studies). Refer to section 7.2 of the REC guidelines
5. References
6. Investigators (CV of each investigator involved)
7. The protocols/proposals are typed using any standard font type, 12-point size, 1.15 line spacing.
8. Consent forms in both English & local language in line with section 5.5.1 of the REC guidelines.
9. If involving children below 15 years or incarcerated people, include an assent form in both English & local language.
10. Data collection tools in both English and local language.
11. Letter(s) of permission of entry from the relevant Institution or Council for the research area(s).
12. Letter(s) of permission of entry/support from relevant District Health Officer (DHO/Head of Health Facility), if the study is going to be conducted in a health facility.
13. Letter of approval from foreign research ethics committee (for all studying in foreign universities)
14. Proof of Payment of the application fee of US$150 or UD$10 or their MKW equivalent.
15. Material Transfer Agreement forms/documents (*If applicable*).

**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 and submit the review and final reports or forms.

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**Signature of Principal Investigator Date**