

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 002: Protocol Assessment/Reviewer Form**

**Research proposals/protocols shall be assessed against the following elements:**

1. **Conformity with Relevant National Policies and Laws**
* For Instance: The National Requirements, Procedures, Guidelines, Regulations, National Research Agenda etc

 **2.0 Scientific Validity of the Study**

 **The reviewers will comment on:**

* + Study Rationale or Problem Statement.
	+ Title, objectives, and design of the study if they are in tandem (The ground-breaking nature, ambition, and feasibility of the research project).
	+ Suitability of proposed methods to address objectives.
	+ Suitability of study population.
	+ Sample size (calculation).
	+ Sampling procedures.
	+ Data Collection techniques in light of the objectives and design of the study.
	+ Data analysis methods.
	+ Ethical validity of the research
	+ Privacy and Confidentiality issues (in light of the study design and its sensitivity) How will privacy and confidentiality be assured for participants?
	+ The adequacy of the Informed Consent Form/Information Sheet (Does it include all the required elements?)
	+ Have all risks, if any, been identified? How will they be managed or avoided altogether?
	+ Benefit (direct or indirect) to participant/institution.
	+ Inclusion and Exclusion Criteria of subjects/participants.
	+ Foreseeable or unforeseeable adverse events if any and how they will be addressed.
	+ Qualifications of the investigator (research team) in light of the proposed study.
	+ Adequacy of the budget to conduct the study.

**PROPOSAL VETTING FORM**

**Name of Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**REC Reference Number for the Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Research proposals/protocols shall be assessed against the following elements:**

**1.0 Conformity with Relevant National Policies and Laws**

* E. g National Requirements, Procedures, Guidelines, Regulations, National Research Agenda etc

**2.0 Scientific Validity of the Study**

**Comment on:**

* Study Rationale or Problem Statement
* Title, objectives and design of the study if they are in tandem.
* Suitability of proposed methods to address objectives.
* Suitability of study population
* Sample size (calculation)
* Sampling procedures
* Data Collection techniques in light of the objectives and design of the study
* Data analysis methods

**3.0 Ethical Validity of the Study**

**Comment on:**

* Privacy and Confidentiality issues (in light of the study design and its sensitivity) How will privacy and confidentiality be assured for participants?
* The adequacy of the Informed Consent Form/Information Sheet (Does it include all the required elements?)
* Have all risks, if any, been identified? How will they be managed or avoided all together?
* Benefit (direct or indirect) to participant/institution
* Foreseeable or unforeseeable adverse events if any and how they will be addressed.
* Qualifications of the investigator (research team) in light of the proposed study
* Adequacy of the budget to conduct the study.

**4.0 Decision and Recommendation of the Reviewer**

**Decisions:** **(1)** Approved, **(2)** Conditional approval (minor changes for review at secretariat), **(3)** Deferral – major changes (resubmit for full committee review), **(4)** Not approved/Rejected

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**Reviewer’s Signature Date**