



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.

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FOREWORD

In its pursuit of becoming a world-class university, the Lilongwe University of Agriculture and Natural Resources (LUANAR), is committed to delivering internationally high-quality research, which is of lasting academic value, and positively impacts and enriches society. While doing research is the height of intellectual freedom, having a self-governing system based on general rules, values and norms agreed upon by individuals or institutions, is important for the autonomy of science and innovation. Such a system should be embedded within the parameters of the ethical principles and standards outlined in the appropriate national laws and regulatory requirements. Research, consultancy and outreach being one of the core mandates of LUANAR, the University has established a Research Ethics Committee (REC), namely LUANAR-REC. Thus, these general administrative guidelines and standard operating procedures (SOPs) are a statement of LUANAR's commitment to promote compliance of research, consultancies, and outreach conducted at LUANAR with the national regulatory requirements in Malawi as guided by the National Commission for Science and Technology (NCST).

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Vice Chancellor, LUANAR

TABLE OF CONTENTS

FOREWORD	i
1. INTRODUCTION	1
2. GUIDING PRINCIPLES OF ETHICAL RESEARCH CONDUCT	3
3. COMPOSITION OF LUANAR-REC	5
3.1 LUANAR-REC Secretariat	5
3.1.1 REC Secretariat Administrator	5
3.1.2 The Compliance Officer	6
3.1.3 Administrative Assistant	7
3.2 LUANAR-REC Members	7
3.2.1 Appointment of members and tenure of office	8
3.2.2 Ensuring Continuity	9
3.2.3 Tenure of office	9
3.2.4 Appointment of the Chairperson and Vice Chairperson	9
3.2.5 Invitation of experts to support reviews	10
3.2.6 Confidentiality agreement	10
3.2.7 Training and orientation of members	10
3.2.8 Termination/disqualification of membership	10
3.2.9 Member resignation	11
3.2.10 Conflict of Interest	11
3.2.11 Compensation for members	12
3.2.12 Audit	12
4. MEETINGS OF THE REC	13
4.1 Scheduling of meetings	13
4.2 Materials for the meeting	13
4.3 Quorum	14
4.4 Decisions at meetings	14
5. REC RESEARCH REVIEWS, PROCEDURES, CRITERIA AND ACTIONS	14
5.1 Applications for REC review	14
5.1.1 Application for new studies and requirements	14
5.1.2 REC proposal format	15
5.1.3 Processing at the Secretariat	15
5.1.4 Amendments/modifications	16
5.1.5 Continuing Review	16

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

5.2	Types and Levels of Review	16
5.2.1	Expedited Review	17
5.2.2	Exemption from review	17
5.2.3	Determination of Type of Review	17
5.3	REC Actions Following Study Review	17
5.3.1	Approval of research	18
5.3.2	Stipulated minor changes	18
5.3.3	Deferral	18
5.3.4	Not approved	18
5.4	REC mechanism of review	18
5.4.1	Completion of the study	18
5.4.2	Suspension and/ or Termination of Study	19
5.4.3	Reporting of Adverse Events	19
5.4.4	Elements of Protocol Review	20
5.5	Informed Consent for Participants	20
5.5.1	Basic Elements of an Informed Consent	21
5.5.2	Translation of Informed Consent	22
5.5.3	Verifying Subject consent	23
5.5.4	Exceptions and Waiver of Consent	23
5.5.5	Research involving vulnerable populations	23
6	REVIEW OF STUDIES OF NATIONAL INTEREST AND CLINICAL STUDIES	25
7	FINANCING AND FEES	25
7.1	Financing	25
7.2	Fees	26
8	LUANAR-REC INSPECTION FOR COMPLIANCE	26
8.1	Submission of reports	27
8.2	Inspections	27
9	REC Standard Operating Procedures	28
	Approval	29
	APPENDIX	30
	SOP NO.1: Standard Operating Procedure for Distributing LUANAR-REC Documents	30
	LUANAR-REC FORM 001: Confidentiality and Non-Disclosure	31
	SOP NO.2: Standard Operating Procedure for Training and Continuing Education of LUANAR-REC Members and Secretariat	32

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

SOP NO.3: Standard Operating Procedure for Animal Research	34
SOP NO.4: Procedure for Initial Proposal Review	36
LUANAR-REC FORM 002: Protocol Assessment/Reviewer Form	37
SOP NO.5: Standard Operating Procedure for Managing a Proposal Submission	41
LUANAR-REC FORM 003: Checklist for Principal Investigators When Submitting Research Proposals to REC	43
SOP NO.6: Procedure for Engaging External Reviewer/Expert	45
SOP NO.7: Standard Operating Procedure for Expedited Review	46
SOP NO.8: Standard Operating Procedure for Management of Protocol Amendments	48
LUANAR-REC FORM 004: Request for Amendment/Modification	49
SOP NO.9: Standard Operating Procedure for Annual Continuing Review	52
LUANAR-REC FORM 005: Application for Continuing Review of Research Activity	54
LUANAR-REC FORM 006: Application Enclosures Checklist for Continuing Review	60
SOP NO.10: Standard Operating Procedure for Declaring Conflict of Interest	61
LUANAR-REC FORM 007: Conflict of Interest Declaration Form	62
SOP NO.11: Standard Operating Procedure for Inspection and Monitoring of Approved Protocols	63
LUANAR-REC FORM 008: Inspection and Monitoring of Approved Protocols Form	64
SOP NO.12: Standard Operating Procedure for Managing Non-Compliance by Investigators	69
SOP NO.13: Standard Operating Procedure for Premature Termination of Protocols	70
LUANAR-REC FORM 009: Termination Notification Form	71
SOP NO.14: Standard Operating Procedure on Payment of Fees in Respect of the Review and or Approval of a Research Protocol	72
SOP NO.15: Standard Operating Procedure for Storage of Active Files	74
SOP NO.16: Standard Operating Procedure for Convening an Extra-ordinary meeting	75
SOP NO.17: Standard Operating Procedure for Management of Participant's Complaints	76
SOP NO.18: Standard Operating Procedure for Material Transfer Agreement	77
LUANAR-REC FORM 010: Material Transfer Agreement Form on Shipping of Samples	78
SOP NO.19: Standard Operating Procedure for Documentation of Meetings	82
SOP NO.20: Standard Operating Procedure for Audit of LUANAR-REC	84
SOP NO.21: Standard Operating Procedure for Review of Guidelines and Procedures	85
SOP NO.22: Standard Operating Procedure for Providing Feedback to Researchers Post-Ethics Review	86

I. INTRODUCTION

The ability of mankind to adapt to quick changes in technology, ideologies, society, and the environment heavily depends on research that develops novel strategies or approaches. LUANAR is one of the public universities in Malawi whose objective is to generate knowledge that should advance innovation and welfare. Through teaching, community involvement and related services, LUANAR is founded on solid research. As such, the university makes constant efforts to ensure that the research carried out by its staff, students and partners plays a key role in resolving development challenges affecting Malawi and beyond borders.

While doing research is the height of intellectual freedom, having a self-governing system based on general rules, values and norms agreed upon by individuals or institutions, is important for the autonomy of science and innovation. Such a system should be embedded within the parameters of the ethical principles and standards outlined in the appropriate national laws and regulatory requirements. Research, consultancy and outreach being one of the core mandates of LUANAR, the University has established a Research Ethics Committee (REC), namely LUANAR-REC. This complies with the national regulatory requirements for establishing, approving, and operating research ethics committees in Malawi, as issued by the National Commission for Science and Technology (NCST).

The mandate of the LUANAR-REC is to safeguard ethical and welfare standards in all research and consultancy activities involving human studies and animal subject research across all faculties and conducted by faculty members, staff, students, and their associates or collaborating partners. LUANAR-REC, therefore, is an institutional research ethics committee supporting all those involved in research, research-related consultancies and projects at LUANAR by ensuring that such undertakings are within the acceptable scope of ethics and science. Specifically, the LUANAR-REC shall;

- Review and approve for ethics and science merit research protocols from all LUANAR faculty members, staff, students and their collaborators and affiliates;
- Perform ethics review and clear all studies involving animals as subjects conducted by LUANAR Faculty, staff, and their collaborating partners;

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

- Protect the safety, rights, privacy and confidentiality of human research participants in research approved by LUANAR-REC;
- Protect the welfare and rights of animals involved in animal subject research;
- To inspect approved human and animal research proposals to ensure that they are implemented in a manner in which they were approved and are in line with ethical standard guidelines;
- Conduct annual continuing reviews of approved studies to ensure the continued safety, rights and wellbeing of study participants;
- Receive, investigate and review complaints related to violation of ethics in human and animal subject research under LUANAR-REC approved research;
- Suspend or terminate any human and animal subject research by staff, students or other researchers cleared by the LUANAR-REC that is not being conducted in accordance with the REC's requirements;
- Work with the National Commission for Science and Technology (NCST) to build the capacity of LUANAR faculty members, staff, and students on research ethics;
- Perform any other duty geared towards the protection of participants in human and animal subject research.

Within the LUANAR-REC mandate, the committee's guidelines shall serve the purpose of aiding the secretariat, its members and researchers/investigators on general procedures, while adhering to the existing national laws and universally acceptable norms, standards and declarations in research. These administrative guidelines are to be used in tandem with the committee's specific Standard Operating Procedures (SOPs) and the Framework of policy guidelines and regulatory requirements on the conduct of research as issued from time to time by the NCST.

The LUANAR faculty members, staff, students, and their associates or partners shall uphold and comply with these guidelines and SOPs to ensure the welfare of humans and animals involved in research to promote credible research results, both at national and international levels. The LUANAR-REC shall grant the ethics approval of a research or project proposal/protocol before the commencement date and in line with the established SOPs.

2. GUIDING PRINCIPLES OF ETHICAL RESEARCH CONDUCT

To guarantee that it carries out its mandate freely and without hindrance, LUANAR-REC will be guided in its operations by the following principles:

2.1 Integrity

Trustworthiness and reliability must be the cornerstones of research. Research conduct must exhibit integrity and moral behaviour that is open and transparent about conflicts of interest. The LUANAR-REC shall be guided by honest, ethical standards and fairness in all its activities in line with the university policies and guidelines, legal frameworks and universally acceptable norms, standards, and declarations in research.

2.2 Professionalism

LUANAR promotes a working environment where faculty members, staff, students, and their associates or partners uphold care, dedication, and a feeling of responsibility, and provide their very best effort in terms of skills, expertise, and experience to every client. Therefore, LUANAR-REC will maintain professionalism in executing its mandate.

2.3 Relevance

All research must address an important question relevant to the morally and ethically acceptable objectives in advancing knowledge, education, science, and human and animal welfare. Research should be based on a plausible hypothesis and have a reasonable prospect of yielding good results. The LUANAR-REC shall be guided by relevance in review and approval of all research, research-related consultancies and projects at LUANAR.

2.4 Innovativeness

In accordance with the policy on research and consulting, students and staff members should use the knowledge they have acquired to carry out research that is innovative and must constantly improve and adapt to society's changing needs. As such, the REC will safeguard ethical standards and procedures in such innovations.

2.5 Independence

To ensure that adequate and appropriate safeguards are instituted, the REC shall always strive to perform reviews and make decisions that shall be independent of political, institutional,

professional, personal, and market influences. This is to protect the safety, rights and wellbeing of human and animal subjects.

2.6 Responsiveness

Research has to be ethically responsive to contemporary and scholarly needs where appropriate, in line with emerging issues and needs to find timely solutions to challenges. The REC shall balance the interests and needs of researchers and the national regulatory requirements and applicable laws.

2.7 Open to diversity

The LUANAR-REC shall promote an inclusive research environment, which is open and welcoming to diverse people, ideas, and perspectives, within the ethical principles.

2.8 Animal Interest

Scientists and educators are obligated to uphold animal interests in the use of laboratory animals. Scientists and educators are expected not to use or kill animals for trivial, irrational, unjustified or inappropriate reasons and not to unnecessarily repeat experiments with outcomes already known or are predictable. The REC shall strive to protect animal welfare and interest in research.

2.9 Humaneness

Humaneness in animal research includes the replacement of animals with non-sentient research systems, reduction of the number of animals which are to be used to a minimum by design and refinement of the experimental methodology to least distressing or harmful effect to the animals. Everyone using animals, whether for experiments, testing diagnosis, teaching, or sourcing of tissues or body fluids is responsible in their personal capacity for assuring that the animals which they use are afforded the highest levels of welfare and protection from abuse and violations of the interests accorded to them. The LUANAR-REC will safeguard ethical standards and procedures in such research to ensure animal protection.

3. COMPOSITION OF LUANAR-REC

LUANAR-REC shall be composed of the Secretariat and Members.

3.1 LUANAR-REC Secretariat

The Secretariat is comprised of the REC Secretariat Administrator, the Compliance Officer, and the Administrative Assistant.

3.1.1 REC Secretariat Administrator

The REC Secretariat Administrator will be the Head of the REC Secretariat and will be responsible for the day-to-day administration and operations of the REC. The Administrator shall be responsible for coordinating research protocol submissions and review and shall provide technical assistance as well as advisory services to investigators and REC members on REC Guidelines and SOPs, applicable national policies, regulatory requirements, and laws. The Administrator shall also provide recommendations for improving the REC review processes, where necessary.

The administrator shall perform the following duties:

- Coordinate and administer LUANAR's Research Ethics Committee;
- Provide ethics consultation services to faculty, staff, students, and researchers;
- Give guidance and advice for designing, writing, and submitting human and animal research ethics protocols;
- Provide research ethics related training and education for faculty, staff, students and researchers;
- Advise researchers in their preparation of notifications of adverse events, protocol violations and deviations, progress and final reports;
- Schedule and organize REC committee meetings, prepare and manage agendas, meeting papers and minutes, disseminate meeting outcomes and maintain records;
- Continuously monitor human and animal research ethics committee memberships to ensure membership and quorum are current, and develop and foster collaborative working relationships with and amongst the members;
- Train and promote awareness of human and animal research ethics issues among faculty researchers and students;

- Ensure compliance requirements by external and internal regulatory bodies regarding human and animal research ethics, including annual reporting, monitoring of approved research, and compliance and follow-up on related issues;
- Resolve issues and enquiries, including investigating and managing complaints relating to human and animal research ethics and coordinating with the relevant committee chairpersons;
- Facilitate audit of LUANAR's Research Ethics Committee activities;
- Develop, implement, and update human and animal ethics online resources for researchers.

3.1.2 The Compliance Officer

The compliance officer will determine whether research that has been approved by REC is being carried out in conformity with LUANAR-REC policies and applicable regional, national, and global standards.

The main duties of the Compliance Officer shall include:

- Ensuring that investigators conduct research following the protocol as approved by REC and in accordance with national regulatory requirements and policies;
- Inspect on-going studies through conducting inspection visits with at least a member of REC;
- Preparing reports of site inspection visits for the REC;
- Take part in the training of REC members and investigators in research ethics and standards;
- Provide advisory services to REC members and investigators on good research practice;
- Ensure the protection of the rights, safety, and wellbeing of research participants;
- Assist/deputize REC Administrator in the discharge of duties including screening of application packages (i.e., protocols) in line with REC Guidelines and SOPs, and national regulatory requirements;
- Ensure that serious adverse events are properly documented and reported to the REC and relevant national regulatory bodies;

- Ensure that all Material Transfer Agreement forms are completed appropriately;
- Ensure that all annual progress reports/continuing review applications are completed;
- Ensure filling and maintenance of study files.

3.1.3 Administrative Assistant

- Filing and record management:
 - Managing filing system, sorting and filing documents according to the filing index, retrieving files when needed and closing them when full.
- Drafting, typing and printing letters, memos
- Coordinating meetings
 - Venue bookings, refreshments and lunch bookings, processing substance allowances
- Supervision
 - Supervises the cleanliness of the surroundings and offices
 - Supervising the Office Assistant: on collection and delivery of mail, use of equipment
- Office management communication:
 - Managing emails and internet facilities- checks and responds to emails
 - Receiving and returning emails, receiving incoming and outgoing mails and responding to them, and disseminating information to all staff and students.

3.2 LUANAR-REC Members

Members of the LUANAR-REC must be representatives of faculties with a responsibility to advance ethical research and safeguard those subjects who take part in it. Members of the committee must come from a variety of disciplines and be sufficiently knowledgeable to carry out committee duties, such as reviewing different research proposals. Directors of research, Directors of Research Centres; Directors of Research Affiliate Centres at LUANAR; Deans of Faculties, and the Executive Management that includes VC, DVC, and Registrar must not be LUANAR-REC members in order to reduce the incidence of primary conflicts of interest. In addition to LUANAR faculty members, the LUANAR-REC should have an independent person(s) not working with LUANAR to be identified as a lay member sitting on the committee. This is also a person(s) with a responsibility to advance public interest, ethical research, and safeguarding research subjects in general.

Apart from having the professional expertise required to evaluate particular research protocols, LUANAR-REC members must also be able to determine whether the proposed research is acceptable in light of national policy commitments, rules, applicable laws, and standards of professional conduct and practice. There should be one or more individuals present who are aware of and experienced in working with vulnerable participants, such as children, convicts, or people with special needs when the proposed research involves them. For research proposals involving biomedical and clinical animal subject research, representation of relevant expertise by faculty members must be adhered to at all times.

The specific membership of LUANAR-REC shall ideally include a total of 14 members with two members from each faculty representing the faculties within the university and 2 lay members. This is specified as follows:

- i. Two representatives from the Faculty of Agriculture
- ii. Two representatives from the Faculty of Development Studies
- iii. Two representatives from the Faculty of Veterinary Medicine
- iv. Two representatives from the Faculty of Food and Human Science
- v. Two representatives from the Faculty of Natural Resources
- vi. Two representatives from the Faculty of Life Sciences
- vii. Two lay members that will be suitably identified.

3.2.1 Appointment of members and tenure of office

The Vice Chancellor's office or any institutionally designated office within the highest rank of LUANAR, shall appoint the members of LUANAR-REC, provided that such an office is pertinent to issues of human and animal subject protection in research. A list of individuals suggested for membership from inside LUANAR, along with their resumes, will be provided by the Secretariat to the appointing authority.

Upon acceptance of the appointment, members shall commit to upholding the following desirable qualities;

- Respect for divergent opinions;
- Relevant experience and education;

- Commitment and motivation;
- Human and animal interest;
- Integrity and diplomacy;
- Confidentiality of all business of the committee.

3.2.2 Ensuring Continuity

When choosing new members to make up the next LUANAR-REC, the appointing authority shall try, in conjunction with the REC Secretariat, to retain at least one-third of the current members to ensure continuity.

3.2.3 Tenure of office

A properly established committee has a three (3) year term from the date of appointment. A committee must be dissolved once its term expires in order to appoint new members and grant them a new term. Members of LUANAR-REC who may have been reappointed are only permitted to serve for a maximum of three (3) terms in a row when continuity is taken into consideration, as stated in section 3.3.2.

3.2.4 Appointment of the Chairperson and Vice Chairperson

The committee members will vote for the chairperson and vice chairperson from among themselves. The chair and vice chair must be somebody who can command the respect of the committee members and the research community. They must also be people who are likely to be dedicated to completing other tasks related to the committee's TORs, in addition to protecting human and other research subjects. The tenure of a properly constituted committee shall be the term of office, as stated in section 3.3.2.

Elections must be held to fill any vacancies in the positions of the chairperson or vice chairperson within the time left before the committee dissolves. If the position of chairperson becomes vacant, the vice chairperson will immediately assume the position on chairperson. If the position of vice chairperson becomes vacant, members must vote on this position. Any member who has to be replaced must complete the same nomination and appointment process as indicated in section 3.2., but they must serve out the remaining time before the committee is dissolved.

3.2.5 Invitation of experts to support reviews

Each committee may create a permanent roster of experts whose knowledge may not be present on the committee while building on the preceding roster of experts. However, specialists on the standing list are not expected to be committee members; rather, they are expected to offer their professional judgment on a research proposal for which the committee has the necessary competence.

Similar to this, in certain exceptional cases, the committee may, with the chairperson's approval and the members' prior knowledge, invite individuals with expertise in particular fields to meetings of REC in order to aid in the review of protocols that call for specialized knowledge not already present on the committee. If they attend any REC sessions, they will not be allowed to vote or be counted toward the quorum. These individuals will be known as External Reviewers.

3.2.6 Confidentiality agreement

All committee business must be kept confidential by the members who serve on REC. Therefore, members will sign a confidentiality agreement that will be made accessible by the secretariat upon appointment to REC and at the first regular meeting. Visitors present during the REC meeting deliberations and any external reviewers that the chairperson appoints through the secretariat to examine a particular study, must likewise sign a confidentiality agreement.

3.2.7 Training and orientation of members

The secretariat shall arrange an induction for committee members to become familiar with REC operations, before they are granted reviewer responsibilities once the committee has been established for the specified term of office. Members must thus go through REC orientation seminars addressing the committee's guidelines and SOPs as well as any practical issues. In essence, all members must go through induction/orientation prior to the first meeting of a properly formed committee.

3.2.8 Termination/disqualification of membership

If the secretariat and LUANAR management consider that a member is unable to fulfil his or her obligations as a REC member, the appointment to REC may be removed prior to the end of the

three-year term. The following conditions will result in the termination or disqualification of REC membership:

- i. Unsound mind.
- ii. A grave breach of conduct like corruption, confidentiality, non-observance, conflict of interest, and failure to attend meetings of REC for three consecutive times without proper reasons.
- iii. Violation of committee's procedures and guidelines, regulatory standards, requirements, and applicable law.

3.2.9 Member resignation

A member must voluntarily resign from the committee in writing to the REC Secretariat when leaving Malawi for an extended period of time and becoming unable to serve on the committee. The secretariat must suggest that the member's appointment be terminated. A replacement is sought if there is no voluntary termination, but a prolonged leave of absence is noted.

The REC members may voluntarily leave the committee at any time. The resignation must be sent in writing through the REC Administrator to the hiring authority, with copies going to the chairperson. In the event that a person permanently leaves or no longer works with LUANAR, their membership on the committee will end automatically, and a suitable replacement will be named.

3.2.10 Conflict of Interest

When the REC is reviewing a proposal in which a member has a specific conflict of interest (either a positive or negative interest), the member in question is required to disclose the specifics of the conflict. In such a situation, the concerned member shall withdraw from consideration of the protocol and shall vacate the meeting room prior to consideration of that specific research protocol/project. A Conflict of Interest Declaration Form supplied by the Secretariat will be required from him or her to sign. It is expected that the Secretariat will record such an action in the minutes. The minutes of the meeting must include a record of the disclosure of any conflicts of interest.

Conflicts of interest could include but are not limited to:

- A member of REC who serves as an investigator/collaborator on research under consideration by REC;
- A member who holds a significant financial interest in a sponsor or phenomenon under study;
- A member whose spouse or close relative has the research under review by REC;
- A member who has any other special form of relationship with the investigator or sponsor of the research under consideration if such a relationship is likely to influence the decision of the committee.

The committee reserves the right to determine or ascertain any other forms or instances of conflict of interest.

3.2.11 Compensation for members

The foundation of membership is the idea of selfless public service to the country. In light of this, members are not entitled to financial payment for their service. However, members are entitled to lodging coverage, a subsistence allowance, and a sitting-in payment at a rate that will occasionally be decided by the institution. With regard to all donations, REC should uphold the letter and spirit of the agreement reached between the university and the donor regarding the payment of allowances, accommodation coverage, and other relevant expenditures as may be necessary. In order to facilitate meetings, the secretariat will make arrangements for food and/or drinks.

3.2.12 Audit

LUANAR-REC is an institutional research ethics committee supporting all those involved in research grants and contracts for projects and consultancies at LUANAR. The REC shall be subject to internal and external audits in compliance with universally agreed laws and regulations by the LUANAR management and/or issued through NCST.

4 MEETINGS OF THE REC

4.1 Scheduling of meetings

Within two weeks of being appointed, a newly formed REC must call a meeting to elect officers from among the members, including the Chairperson and Vice Chairperson.

If the final Wednesday of the month is not a public holiday, REC will convene an ordinary meeting on that day each month. If such a day is a public holiday, the secretariat must organize a meeting within that week. The committee shall convene an extra-ordinary meeting where necessary, provided the quorum requirements are fulfilled. The committee shall convene an expedited committee meeting where necessary provided members of the expedited committee are available. The REC secretariat is in charge of scheduling meetings.

The secretariat is responsible for making sure that the members are informed well in advance of the scheduled meetings through print and other electronic media. REC retains the authority to adjust the intervals for regular meetings based on the intensity and number of proposals. However, extra-ordinary meetings may be called at the chairperson's discretion, at the demand of at least half the membership, or on the recommendation of the secretariat.

4.2 Materials for the meeting

The Secretariat of the committee processes all research proposals submitted for assessment as well as all other materials relating to the committee meeting. Research proposals must be provided to committee members at least two weeks before a scheduled meeting to allow members ample time to study the submitted documents.

Complete proposals must use the LUANAR-REC submission guidelines, which include:

1. Protocol;
2. Consent forms;
3. Data collection instruments like questionnaires translated into a suitable local language if necessary;
4. CVs for the research team;
5. Any other relevant information as indicated in the REC proposal submission checklist.

4.3 Quorum

A minimum of 60% of the REC membership is required for an ordinary quorum. If a quorum cannot be attained, the meeting is postponed for the next two weeks. At this rescheduled meeting, if no ordinary quorum is reached, the chairperson shall make a decision based on the expertise and number of members present; otherwise, the meeting will be rescheduled for the next regular meeting. A minimum of 70% of Expedited Committee members is required to have an expedited meeting where necessary.

4.4 Decisions at meetings

At REC sessions, decisions are made by consensus. If no agreement is reached, a decision is taken by the simple majority of those in attendance through a secret or open vote. If there is a tie, the committee will decide in accordance with its applicable SOPs. But even if the opposite viewpoint comes from a small portion of the membership, strict assessment of the ethical and legal justification of the topic under discussion must always be taken into account before a decision is made.

5 REC RESEARCH REVIEWS, PROCEDURES, CRITERIA AND ACTIONS

Research proposals that meet the committee's guidelines will be evaluated by the REC. Proposals that don't meet the requirements must be referred back to the researchers for revision, and then they must be submitted once they are complete.

5.1 Applications for REC review

5.1.1 Application for new studies and requirements

The requirements for the REC format are outlined in the REC submission checklist and Standard Operating Procedure (SOP) for the review of proposals, and they must be met by all applicants.

Foreign researchers must be linked with a local institution, and documentation of this affiliation must include a letter of support from the affiliated institution, and that they will also work with a local partner. A local collaborator is not required but at the very least, a local affiliation is required for a foreign student researcher.

A complete submission package for a new study must adhere to all the necessary requirements on the **REC checklist** and any **related Standard Operating Procedure(s)**.

Applications may be submitted at any time to the secretariat. An electronic copy should be submitted to the following E-mail address: luanarrec@luanar.ac.mw.

For enquiries the REC secretariat office is located at the Gateway Administration building – Bunda Campus. The official mailing address is as below:

The Secretariat,
LUANAR Research Ethics Committee,
P.O Box 219,
Lilongwe, Malawi.

All incomplete submissions shall not be reviewed based on the checklist for submission form. The REC secretariat will inform the applicant to submit the missing documents or resubmit the application.

5.1.2 REC proposal format

The REC mandates that protocols be guided and submitted using the format outlined in its proposal submission check list (Form 003) and guided by the Standard Operating Procedure on initial proposal review. The REC Secretariat can provide more guidance.

5.1.3 Processing at the Secretariat

All applications will be initially screened by the secretariat for completeness, and it will make a preliminary judgment based on the items on the checklist and the normal operating procedure for handling protocol submissions. The SOP for managing protocol submissions and other pertinent SOPs will be followed in making the final decision about the type of review. The submission will be given a REC proposal number once a complete package of information has been received and it has been determined that the study does not meet the requirements for exemption. For the purpose of easy referencing, this assigned number is used throughout the research process for REC regulatory records and files.

5.1.4 Amendments/modifications

Changes to the first approved study are referred to as amendments or modifications. Any suggested modification to research that has already received approval must be presented as an amendment to that study, and it will be evaluated in accordance with the SOP for handling amendment requests. Applications for amendments must be made on a Request for Amendment Form.

5.1.5 Continuing Review

All approved studies that last longer than a year are continually reviewed by REC. The REC will examine these ongoing, approved studies once a year. A unique continuing review application form, available at the secretariat, must be used to request continued review. A progress report that is part of the application for continuing review provided in the SOPs must include information from the Principal Investigator (PI) about the number of subjects enrolled, any issues that sprang up during the preceding approval period, and other matters as typically outlined on the form.

The study will be considered lapsed and inactive if the principal investigator does not submit the materials for further review within one month after the expiration date. The REC will issue an order to immediately stop all study-related operations, with the exception of those required for the wellbeing of the human participants and animal welfare, once a study has expired.

The principal investigator must submit a fresh application for REC evaluation and wait for approval before starting research under the protocol if the study has been on hold for more than two months. Otherwise, the study would be deemed to have ended, and the principal investigator will be asked to specify the methods to be used for subject monitoring.

5.2 Types and Levels of Review

A fully constituted REC will typically assess any new studies. The following research will be assessed by a full REC, notwithstanding elements of SOPs for full committee meetings and expedited reviews;

- All high-risk studies
- Studies involving vulnerable populations (including pregnant women, prisoners, mentally incompetent patients etc)

- Studies involving sensitive information connected to personal identifiers
- Studies previously reviewed but require major issues to be addressed
- Studies on nationally sensitive topics

In unusual cases, the committee may schedule an open meeting when an investigator is asked to address specific concerns about their protocol. After being heard, the investigator will immediately leave the meeting space. Thus, a closed session will be used to decide on that protocol (i.e. after the investigator has walked out of the room).

5.2.1 Expedited Review

According to the relevant SOP, research investigations that have already been thoroughly examined by a committee and just need the principal investigator to correct minor flaws may be approved through the expedited method. However, those requiring major issues to be addressed would be forwarded to a full committee meeting. Depending on the received volume of undergraduate research studies and those considered by the chairperson through the secretariat to be time sensitive, these studies will undergo an expedited review.

At the following ordinary scheduled meeting, the secretariat shall advise members of any research proposals that have been approved through expedited review and provide members with a brief synopsis of each expedited protocol.

5.2.2 Exemption from review

There aren't any requirements for study exemptions from ethics review at the moment.

5.2.3 Determination of Type of Review

The secretariat will screen the full application and recommend the necessary review process to the chairperson or vice chairperson of the REC.

5.3 REC Actions Following Study Review

The committee through the REC secretariat must notify the review decision to the investigator in writing within seven (7) working days after the committee review meeting.

5.3.1 Approval of research

In the case of approval with no changes, the committee through the REC secretariat shall inform the investigator in writing as indicated above. The communication will include an officially stamped approved consent form and other related documents.

5.3.2 Stipulated minor changes

The REC will decide and notify the investigator if a study can be accepted with the required minimal adjustments or clarifications. If these little adjustments or clarifications are made, such research will also be eligible for expedited review. Minor modifications/clarifications don't have the ability to put human beings or animal subjects at higher risk or reduce research benefits.

5.3.3 Deferral

If the study requires major adjustments or clarifications, the review will be postponed to a full committee meeting before approval can be given.

5.3.4 Not approved

The study will not be accepted, and the investigator will be informed of the reasons if a proposal calls for significant changes that are unlikely to be possible without a thorough rewrite of the proposal.

5.4 REC mechanism of review

The secretariat will designate three lead reviewers for each proposal based on their areas of expertise as the primary, secondary, and third reviewers. The reviewers can be drawn from the members of REC or External Reviewers as indicated in section 3.3.4, based on their area of competence.

5.4.1 Completion of the study

When the study is over, the investigator must provide written notice of completion. The investigator must deliver the final technical report after the investigation is finished. An electronic copy must be submitted to the secretariat using the email address: luanarrec@luanar.ac.mw which will be uploaded on the LUANAR-REC web-based server.

5.4.2 Suspension and/ or Termination of Study

In the event of an unfavourable incident, noncompliance, or another threat to human and animal subjects, the REC may cease the study at any moment, subject to further examination or analysis. Protocols can also be terminated at the request of the Principal Investigator when subject enrolment and subject follow-up are discontinued.

At the following scheduled meeting, the study will be examined to see if any revisions are necessary. The REC is required to provide written notice with reasons for suspension or termination to the Principal Investigator and the research sponsor, with a copy sent to the LUANAR office in charge of research affairs.

In the case of any documented major adverse events and any unforeseen issues that are documented by the researcher, REC shall halt the study and direct the investigator to monitor study participants or the community. The study will be suspended by REC to safeguard the safety of the human and animal subjects and conduct an inquiry in the event of any officially and unofficially reported non-compliance, protocol violation, or deviation by the researcher. If the convened REC is convinced beyond a reasonable doubt that there was non-compliance, deviation, or violation of the protocol after investigating the issue that led to the study's suspension, the study will be terminated.

The REC will undertake a continuing review and reactivate any protocol if the investigator provides the materials for continuing review as specified in section 5.1.5. A new approval period is established as a result of this reactivation.

5.4.3 Reporting of Adverse Events

An unfavourable event or adverse experience is an unwanted and unanticipated damage or physical or emotional effect on a human being or animal. Serious adverse events are defined as those that are fatal or life-threatening, resulting in significant or long-term disability, necessitating or prolonged hospitalization, resulting in a congenital anomaly/birth defect, or representing other significant hazards or potentially serious harm to research subjects or others in the investigators' opinion.

The term "unexpected and unanticipated" refers to adverse outcomes or other problems in the research whose kind and/or severity do not match the information previously supplied to REC. For the occurrence of an adverse event, the REC requires the investigator to present a written report.

The following information must be included in the report:

- Title of protocol;
- REC assigned reference number;
- Name of the investigator;
- Local affiliating institution for studies originating outside Malawi;
- Subject identifier;
- Date and site/place of the event;
- Description of event (i.e. nature of the injury or other adverse occurrence, severity assessment, and assessment of the event's relationship to the study);
- The action taken by the researcher; and
- Signature of the principal investigator.

5.4.4 Elements of Protocol Review

The aspects of the research protocol review must adhere to the REC SOP on the initial proposal review and the associated forms. On the one hand, these aspects are generally legal, regulatory, and policy in nature, while on the other hand, they are ethical and scientific in nature.

5.5 Informed Consent for Participants

Any person who receives an invitation to engage in a research study must be provided with a sufficient description of the study that is detailed and comprehensive enough for the person to decide if she or he wants to participate. The informed consent procedure should be set up to give prospective participants information that is simple to understand in a quantity and at a pace that will ensure their understanding.

Unless REC waives it, consent must be obtained from every subject who is legally, psychologically, and physically capable of giving it. Parents, legal guardians, or any other of their legally appointed representatives, should be asked for consent on behalf of persons who are not mentally, physically, or legally capable.

Consent must be given in writing unless REC determines that written documentation of informed consent may be disregarded. The wording used in consent forms and other informational documents, such as information sheets, should be straightforward to make them understandable to potential participants and anyone without technical knowledge in the field. If a prospective participant cannot read or understand the written permission form's wording, REC shall permit oral or verbal consent. The script or information sheet, however, must be approved by REC and signed for by the possible participants' parents, legal guardians, or other legally appointed representatives.

Any written or verbal informed consent must not contain any exculpatory language that would cause the subject, or the subject's authorized representative, to lose, waive, or appear to lose any of their legal rights, or that would release the researcher or sponsor from liability for negligence or any unfavourable outcomes resulting from their participation in the study.

All participants must physically or electronically sign to approve a permission form or document that has all necessary components of informed consent. This is the typical expectation. For those who are illiterate and unable to consent, a witness can sign or approve on their behalf. Parents, legal guardians, or other designated legal representatives must physically or electronically sign or approve on behalf of minors who are unable to consent legally, mentally, or physically.

Minors who are capable of giving permission must give their consent before participating in a study. REC shall consider the children's ages, levels of maturity, and psychological states when assessing whether they are able to assent. Minors must, however, consent in addition to parental approval. In some circumstances, REC may consider minors' acquiescence to be informed consent. Commonly, these minors get emancipated. These emancipated children could be university students younger than Malawi's legal adult age of 18, minors who are lawfully married, or minors whom society may view as mature minors.

5.5.1 Basic Elements of an Informed Consent

Unless REC permits exceptions when requesting informed consent from participants, any consent form is anticipated to include at a minimum the following components:

- A statement that the study involves research;

- Explanation of the purposes of the research;
- Expected duration of the subject's participation in the research;
- Description of the procedures to be followed;
- Identification of any procedures that are experimental or otherwise;
- Description of any reasonably foreseeable risks or discomfort to the subject;
- Description of any benefits to the subject or to others that may reasonably be expected from the research;
- Disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be kept and maintained;
- An explanation of who to contact for answers to pertinent questions about the research and research subject's rights, and who to contact in the event of a research-related injury to the subject, if relevant.
 - Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human and animal subjects should be referred to the REC Chairperson through the secretariat. The secretariat will provide contact details of the sitting REC Chairperson.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled;
- For research involving more than minimal risk, an explanation as to whether any (insurance) compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- Name, signature and date space.

5.5.2 Translation of Informed Consent

In the informed consent procedure, both oral interpretation and textual translation should be considered. A qualified individual who is not a family member of the potential subject should perform oral interpretation for verbal consent. The person doing the interpretation should be available for continuous dialogue between subjects and investigators.

A qualified person should translate informed consent forms into written forms. In this context, the investigator should exercise great effort in locating a qualified translator who can provide a competent translation of the informed consent forms. Back translations to English are required to validate the translation's accuracy. REC will review all back translation materials.

5.5.3 Verifying Subject consent

Prior to participating in the study, individuals must sign or approve and date the REC-approved consent form as issued in the approval letter, unless excused by REC.

5.5.4 Exceptions and Waiver of Consent

In exceptional circumstances, the REC may waive the requirement that the investigator obtain signed informed consent. These circumstances may be those stated in Malawi's Framework of Guidelines for the Conduct of Research in the Social Sciences and Humanities.

The REC may mandate the investigator to present participants with a written statement about the research in the form of an information or fact sheet in lieu of a signed permission form. This statement should include, at the very least:

- A description of the level of involvement and amount of time expected from participants;
- A description of the study;
- A description of the risks and benefits to the participants;
- A statement describing the participant's rights;
- Contact information for both the investigator and REC secretariat.

5.5.5 Research involving vulnerable populations

Potential research volunteers who are comparatively or completely incapable of defending their own interests are referred to as "vulnerable populations." As a result, researchers must provide additional protections for these communities' welfare and safety as well as justify the planned inclusion of these people in the study. Some groups are generally viewed as vulnerable research subjects, these include children, expectant mothers, inmates, immigrants, sex workers, and those with mental illnesses. Women in some contexts (for example, some women who traditionally must ask their husbands before consenting to participate in a research study) and people with limited financial resources who may have limited access to health services and may view

participation in a research study as their only opportunity are other vulnerable groups. Primarily, research involving vulnerable populations may be justified on the following account:

- The research is directly related to the specific conditions of the class involved; and
- Subjects or the class of persons to which the subjects belong may benefit from the research.

The following factors must be taken into account in research involving vulnerable persons in order to ensure safeguards, according to REC:

- The methods of recruitment selection and the inclusion/exclusion criteria should be considered by REC, as should informed consent, the confidentiality of data, and the willingness of the subjects to volunteer.
- Group characteristics such as economic, social, physical, and environmental conditions should be considered to ensure that the research includes appropriate safeguards for the protection of vulnerable subjects.
- Applicable national laws, regulatory requirements and policies that bear on the decision-making abilities of potentially vulnerable persons.
- Research studies involving potentially vulnerable subject groups should have adequate procedures in place for assessing and ensuring subjects' capacity, understanding and informed consent or assent.

In reviewing such research and in addition to these elements, REC shall be sensitive to the vulnerability of participants resulting from:

- Unique socio-economic factors: for example, an offer of financial compensation for participation in research may be interpreted as exploitative.
- Cultural factors: these may affect the ability of some subjects to give informed consent. For example, if a chief/local leader has urged participation in research; prospective subjects may not feel free to opt out of the study.

6 REVIEW OF STUDIES OF NATIONAL INTEREST AND CLINICAL STUDIES

The mission of the LUANAR-REC, an institutional research ethics committee, is to protect the safety, rights, and welfare of human and animal subjects in research that is carried out by LUANAR faculty, employees, students, and their associates and partners. All studies that are biomedical/clinical in nature, and involve humans as subjects shall not be reviewed by the LUANAR-REC. This is because biomedical or clinical studies are classified as studies of national interest since they demand special attention due to their delicate, political, and safety-related ramifications. Such studies of National Interest will be reviewed by the National Health Sciences Research Committee or by the NCST suitably designated research ethics committee responsible for the review of such studies, provided such a research ethics committee has the relevant jurisdiction stipulated in the regulatory requirements issued by NCST. However, the LUANAR-REC shall have jurisdiction to review and clear all studies involving animal drugs and vaccines as indicated in the SOP on Animal Research. Such clinical animal subject research reviews will ensure a significant representation of experts from the Faculty of Veterinary Medicine, as defined in section 3.2 and sub-section 3.2.5.

Studies in the following fields are an example of "National Interest Studies" and are exempted from LUANAR-REC review:

- All human vaccine trials;
- All human genetic studies;
- All human stem cell research;
- All human cloning research;
- All human national health surveys;
- All human drug trials.

7 FINANCING AND FEES

7.1 Financing

The University shall pay the REC Secretariat's salary. LUANAR-REC operational expenses will be paid from university approved budget, that will include income from REC review and compliance fees. REC money shall be accounted for under the Directorate of Research and Outreach (DRO) account with a prospect of having a separate LUNAR-REC Account.

7.2 Fees

For each proposal submitted for ethical review by faculty members, post-graduate students and their collaborators, an application/processing fee in the amount of USD150 in Malawi Kwacha Equivalent must be paid as per REC regulations and policy as authorized by NCST. For each proposal submitted by undergraduate students at LUANAR, an application/processing fee in the amount of USD10 in Malawi Kwacha Equivalent must be paid as authorized by NCST.

If the protocol submitted by faculty members, post-graduate students and their collaborators is found to be acceptable after evaluation, the investigator must pay a compliance and capacity-building fee equal to 10% of the total budget specified in the specific research study protocol, for operations involving the protection of human and animal subjects. undergraduate protocols are exempted from paying the 10% compliance and capacity building fees.

The compliance and capacity fees are to be used for the day-to-day operations of REC to perform the following research and ethics compliance-related functions;

- Proposal review meetings of REC
- Inspection, compliance, and monitoring of research studies to promote the protection of research subjects in the field
- Promoting capacity building for research within LUANAR
- Supporting continuing education for members of REC on research ethics and integrity
- Organizing research dissemination conferences as a platform for offering feedback to the communities
- Student research grants to encourage young researchers

All payments related to the processing and compliance fees must be paid through the LUANAR Bank Details as advised by the secretariat. Only after paying all the fees and submitting proof of payment to the REC secretariat will an ethical approval and permit be granted.

8 LUANAR-REC INSPECTION FOR COMPLIANCE

After a particular study is finished and closed, a researcher is required to keep all participant study files, including the approved proposals, administered consent forms, collected data, and

approved data collection tools, for a maximum of three years to facilitate the necessary compliance inspection as per the applicable REC SOP on inspection of approved studies.

To ensure that investigators are following the established protocol, REC will undertake monitoring and inspections for all human and animal subject research. The duties of this committee will also include conducting investigations related to research complaints. The inspection process will take the following mechanism:

8.1 Submission of reports

REC members will request reports as follows;

1. Progress report for one-year studies
2. Annual report for medium to long term studies
3. Final report

8.2 Inspections

The full committee and/or other committee members shall conduct periodic inspection visits to the study sites at least twice a year (depending on the volume of on-going studies and available resources). The REC inspection form will be used by members while performing inspection visits.

The inspection team/ full committee shall use the following inspection procedure;

- Meeting principal investigator or co-investigator and study staff;
- The meeting, if applicable with the study co-coordinator;
- If applicable, visit recruitment sites/units, and meet some study participants;
- Checking participant's study files and consent forms etc.

For the purpose of inspecting some particular studies, the REC reserves the power to designate any qualified individual from its permanent list of experts, who is not a member of the committee.

9 REC Standard Operating Procedures

LUANAR-REC Standard Operating Procedures (SOPs) include:

SOP NO.1: Standard Operating Procedure for Distributing LUANAR-REC Documents

SOP NO.2: Standard Operating Procedure for Training and Continuing Education of
LUANAR-REC Members and Secretariat

SOP NO.3: Standard Operating Procedure for Animal Research

SOP NO.4: Standard Operating Procedure for Initial Proposal Review

SOP NO.5: Standard Operating Procedure for Managing a Proposal Submission

SOP NO.6: Standard Operating Procedure for Engaging External Reviewer/Expert

SOP NO.7: Standard Operating Procedure for Expedited Review

SOP NO.8: Standard Operating Procedure for Management of Protocol Amendments

SOP NO.9: Standard Operating Procedure for Annual Continuing Review

SOP NO.10: Standard Operating Procedure for Declaring Conflict of Interest

SOP NO.11: Standard Operating Procedure for Inspection and Monitoring of Approved
Protocols

SOP NO.12: Standard Operating Procedure for Managing Non-Compliance by Investigators

SOP NO.13: Standard Operating Procedure for Premature Termination of Protocols

SOP NO.14: Standard Operating Procedure on Payment of Fees in Respect of the Review and
or Approval of a Research Protocol

SOP NO.15: Standard Operating Procedure for Storage of Active Files

SOP NO.16: Standard Operating Procedure for Convening an Extra-Ordinary Meeting

SOP NO.17: Standard Operating Procedure for Management of Participant's Complaints

SOP NO.18: Standard Operating Procedure for Material Transfer Agreement

SOP NO.19: Standard Operating Procedure for Documentation of Meetings

SOP NO.20: Standard Operating Procedure for Audit of LUANAR-REC

SOP NO.21: Standard Operating Procedure for Review of Guidelines and Procedures

SOP NO.22: Standard Operating Procedure for Providing Feedback to Researchers Post-Ethics
Review

Approval

Deputy Vice Chancellor

Agnes Mbachii Mwangwela, PhD

Name

Signature

Date

Director of Research and Outreach

Samson Pisanazo Katengeza, PhD



15th March 2025

Name

Signature

Date

National Commission of Science and Technology (NCST)

Name

Signature

Date

APPENDIX

SOP NO.1: Standard Operating Procedure for Distributing LUANAR-REC Documents

1. Purpose

This SOP describes how to handle original documents and copies of documents in order to protect the confidentiality of the documents.

2. Scope

- i. Documents: Protocols and related documents, data related to participants, correspondences to and from REC, and minutes of meetings.
- ii. Chairperson and vice chairperson of REC
- iii. REC members
- iv. Secretariat
- v. Consultants

3. Allowable Exceptions

This SOP is meant to be followed without deviation.

4. Procedures

- i. New members, staff, experts, and consultants of LUANAR-REC sign a Confidentiality Agreement at the time of appointment.
- ii. Members of LUANAR-REC are provided with copies of documents through their official emails from the official LUANAR-REC email address.
- iii. Secretariat shall maintain the digital distribution log.
- iv. Members shall not distribute LUANAR-REC documents to non-members and keep all documents secure.
- v. Members shall respect the intellectual property.
- vi. LUANAR-REC shall recommend to the appointing authority the disciplinary action for members and secretariat who fail to adhere to the Confidentiality Agreement.

Definition of Terms

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Protocol: A document that provides the background, rationale, and objective(s) of a research project and describes its design, and methodology, including ethical and statistical considerations.

LUANAR RESEARCH ETHICS COMMITTEE

LUANAR-REC FORM 001: Confidentiality and Non-Disclosure

In the course of your activities as a member of LUANAR-REC, you may be provided with confidential information and documentation (which we will refer to as “Confidential Information”). You agree: to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person, not to use the Confidential Information for any purpose outside the Committee’s mandate, and in particular, in a manner which would result in a benefit to yourself or any third party; and to return all Confidential Information (including any minutes or notes you have made as part of your LUANAR-REC duties) to the Chairperson upon approval of the research protocol by the REC and termination of your functions as a REC member.

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original will be kept on file in the custody of the REC Administrator. A copy will be provided for your records.

I _____ have read and accept the aforementioned terms and conditions as explained in the Agreement.

Undersigned Signature

Date

REC Administrator

Date

SOP NO.2: Standard Operating Procedure for Training and Continuing Education of LUANAR-REC Members and Secretariat

1. Purpose

The purpose of this procedure is to inform LUANAR-REC members and secretariat about essential training and how members can access it. LUANAR-REC recognises the importance of continuing education and training of its members and secretariat in the ethical and scientific review of research proposals. Both old and new members and the secretariat are required to undergo training at the beginning of the new term of office and as the need arises.

2. Scope

This SOP applies to LUANAR-REC members and the secretariat.

3. Allowable Exceptions

This SOP is meant to be followed without deviation.

4. Procedures

- i. All LUANAR-REC members and staff shall receive initial training at the start of the term of office on the following:
 - Functions and operations of LUANAR-REC
 - Research guidelines (Proposal/protocol format)
 - How to conduct scientific and ethical review of protocols
 - Good research practice
 - Conflict of interest and integrity
- ii. The Secretariat shall identify providers of training in consultation with the Director of Research and Outreach.
- iii. The Secretariat shall organize the training and continually provide information about relevant training courses, workshops, and conferences.
- iv. Members may identify an appropriate course and inform the secretariat in writing.
- v. The Secretariat shall keep training records.
- vi. Members and the secretariat shall receive continuing training.

Definition of Terms

Conference: A meeting of individuals or representatives of various bodies for the purpose of discussing and/or acting on topics of common interest.

Good research practice: Internal standards of the way in which research is planned and conducted, results are recorded and reported, and the findings are disseminated, applied and exploited.

Protocol: A document that provides the background, rationale and objective(s) of a research study and describes its design, including ethical and statistical considerations.

Workshop: A group of people engaged in study or work on a creative project or subject.

SOP NO.3: Standard Operating Procedure for Animal Research

I. Purpose

The purpose of this procedure is to describe how animal research is to be conducted.

2. Scope

This SOP applies to Study Participants and investigators.

3.1.1. Allowable Exceptions

This SOP must be followed without deviation.

3.1.2. Procedures

i. Experimental Design:

- Develop a clear and well-defined research plan that justifies the use of animals.
- Minimize the number of animals used while ensuring statistical validity.

ii. Animal Housing and Care:

- Provide appropriate housing conditions (temperature, humidity, light, and ventilation) for the species.
- Regularly clean and sanitize animal enclosures.
- Ensure access to appropriate bedding, nesting materials, and enrichment.
- Provide a nutritionally balanced diet and access to clean water.

iii. Animal Handling:

- Handle animals gently, minimizing stress and discomfort.
- Use appropriate personal protective equipment (PPE) to prevent cross-contamination and protect researchers and animals.
- Minimize noise, sudden movements, and disturbances.

iv. Health Monitoring:

- Regularly monitor animals for signs of illness, injury, or distress.
- Isolate sick animals and provide appropriate veterinary care.

v. **Data Collection and Documentation:**

- Maintain accurate and detailed records of animal-related activities.
- Document experimental procedures, observations, and measurements.
- Keep records of animal numbers, sources, and identification.

vi. **Reporting and Communication:**

- Provide regular updates to the PI on research progress, animal welfare, and any deviations from the plan.

vii. **Disposal and Post-Study Care:**

- Dispose of animal waste and carcasses following approved methods.
- Consider appropriate post-study care, such as the adoption or retirement of animals.

viii. **Training and Education:**

- Ensure all researchers involved in animal studies receive proper training in animal handling, ethics, and relevant techniques.
- Attend mandatory workshops and seminars on animal welfare and care.

ix. **Emergency Procedures:**

- Develop and communicate emergency protocols for animal-related incidents, such as escapes, injuries, or natural disasters.

Definition of Terms

Experimental Design: the process of carrying out research in an objective and controlled fashion so that precision is maximized, and specific conclusions can be drawn regarding a hypothesis statement.

SOP NO.4: Procedure for Initial Proposal Review

I. Purpose

This SOP describes how LUANAR-REC shall review and assess proposals submitted to it for the first time using the Proposal Assessment Form.

I. Scope

This SOP applies to the ethical and scientific assessment of all proposals submitted for review. The specific elements in all the sections of the **Proposal Assessment Form (Form 002)** must be adequately addressed by the proposal under review and/or related documents submitted together with it. The usage of this SOP applies to REC members and any appointed reviewers.

2. Allowable Exceptions

This SOP is meant to be followed without deviation.

3. Procedure

- i. The Secretariat shall send the proposal and the Proposal Assessment Form to the assigned reviewers (Primary, second and third reviewers).
- ii. Reviewers shall submit completed proposal assessment forms to the REC secretariat within **fourteen (14)** days; or seven **(7)** days in the case of an expedited review (See *SOP NO.7 on expedited review*).
- iii. In the case of a full committee review at a scheduled monthly meeting, reviewers should submit the completed assessment forms to the secretariat a day before the ordinary or expedited meeting.
- iv. The primary reviewer shall present the proposal and comment on it, followed by the secondary and third reviewers who only present their comments on the proposal.
- v. REC members shall discuss the proposal and the comments made by the reviewers.
- vi. In case of non-consensus, a vote shall be cast. In case of a tie, the chairperson shall cast a deciding vote. However, the committee shall be mindful of the ethical and legal obligations and principles that numbers shall not always be the deciding factor but together with the quality of the deferring opinion which REC shall always be required to take into consideration in deciding on a proposal. In this regard, the chairperson may seek the opinion of the relevant authority in the study area. Such an opinion would be considered in deciding on a proposal so long as such a given opinion respects ethical and legal principles and obligations.
- vii. The Secretariat shall record the REC decision for feedback to the investigator within **seven (7) working days** after a full committee meeting.

Definition of Terms

Proposal Assessment Form: An official record that documents the proposal review against the standard elements and other ethical and regulatory obligations.

LUANAR RESEARCH ETHICS COMMITTEE

LUANAR-REC FORM 002: Protocol Assessment/Reviewer Form

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

1.0 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:

I.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?

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

- 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

Reviewer's Signature

Date

SOP NO.5: Standard Operating Procedure for Managing a Proposal Submission

4. Purpose

This SOP describes how a research proposal submitted by investigator(s) is processed before being reviewed by LUANAR-REC following the **LUANAR-REC FORM 003**.

5. Scope

This applies to

- i. Packages submitted for the first time to LUANAR-REC for review.
- ii. REC Secretariat
- iii. REC members
- iv. Investigators

3. Allowable Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedures

- i. The Secretariat conducts administrative screening of the application package against the REC checklist within **two working days**.
- ii. Secretariat acknowledges receipt of the online package in writing indicating whether the package complies with the REC guidelines or not.
- iii. If the application package is incomplete the investigator is requested to provide the missing documents/information within **five working days** after notification.
- iv. If the application package is complete, the secretariat:
 - a. Assign proposal reference number.
 - b. Put the proposal on the register and database.
 - c. Assign the review date for the proposal and inform the investigator that the proposal has been accepted for review.
- v. REC secretariat assign the proposal to the primary, secondary and third reviewers based on expertise in the subject area of the study.
- vi. Secretariat submits the package to reviewers **Fourteen (14) days** before the date of the full committee meeting if such a proposal is to be reviewed through an ordinary full Committee Review Procedure (SOP NO.5), which is monthly otherwise an expedited review procedure may be followed as per SOP NO.7.

Definition of Terms

Proposal submission package: The set of documents that includes the protocol and other relevant documents submitted by the investigator when applying for approval from LUANAR-REC. The package should comply with the submission requirements in the LUANAR-REC checklist.

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.

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

1. Covering letter from Principal Investigator ☐
2. Letter of support from ☐
 - a. Head of the Department hosting the research ☐
 - b. 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:
 - a. Title
 - b. Abstract
 - c. Introduction/Background
 - d. Rational/ justification
 - e. Objectives of the study
 - f. Literature review
 - g. Methodology/ Experimental Design
 - Type of study, design, and setting
 - Study population (human and/or animals)
 - Study period
 - Sample size
 - Data collection and management

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

- Data Analysis
 - g. Research dissemination strategy
 - h. 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?
 - i. Workplan
 - j. 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 undergraduate studies). Refer to section 7.2 of the REC guidelines
 - k. References
 - l. Investigators (CV of each investigator involved)
4. The protocols/proposals are typed using any standard font type, 12-point size, 1.15 line spacing. ☐
 5. Consent forms in both English & local language in line with section 5.5.1 of the REC guidelines. ☐
 6. If involving children below 15 years or incarcerated people, include an assent form in both English & local language. ☐
 7. Data collection tools in both English and local language. ☐
 8. Letter(s) of permission of entry from the relevant Institution or Council for the research area(s). ☐
 9. 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. ☐
 10. Letter of approval from foreign research ethics committee (for all studying in foreign universities) ☐
 11. Proof of Payment of the application fee of US\$150 or UD\$10 or their MKW equivalent. ☐
 12. 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;

- i. accept responsibility for the scientific and ethical conduct of this research study,
- ii. obtain prior approval from the REC before amending or altering the research protocol or implementing changes in the approved consent form,
- iii. immediately report to REC any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study,
- iv. train study personnel in the proper conduct of human and animal participant's research,
- v. Complete and submit the review and final reports or forms.

Signature of Principal Investigator

Date

SOP NO.6: Procedure for Engaging External Reviewer/Expert

1. Purpose

To engage services of an external reviewer/expert in a specific area of expertise (e.g. ethics, law, specific diseases or methodologies, community representation, patients, and special interest groups), not available among the Committee members but is applicable to submitted research protocol.

2. Scope

This SOP applies to

- i. Chairman/Secretariat of REC
- ii. REC members and investigators
- iii. External reviewers/experts

3. Allowable Exceptions

- None

4. Procedures

- i. REC shall have a standard list of external reviewers. In addition, members may identify additional reviewers continually as the need arises.
- ii. Members present names of potential experts.
- iii. Experts are approached in writing to serve in that capacity.
- iv. Those who are willing should present their updated CVs which are then, at their second meeting, circulated for member's review and consideration.
- v. The committee formally agrees on qualified experts at their third regular meeting of the year.
- vi. Chairperson through the secretariate submits the list of names of the qualified experts to the Director of Research and Outreach for official appointment as consultants.
- vii. The chairperson through the secretariate communicates to the appointed consultants when the need arises.
- viii. Each external reviewer will sign a Confidentiality and Conflict of Interest Form [See SOP NO. 1].
- ix. Either the external reviewer or REC is at liberty at any point to terminate the engagement of a particular external reviewer, with each party giving the reasons for the discontinuation of the engagement.
- x. The external reviewer can be engaged without limitation of terms of office.
- xi. A newly constituted REC membership will independently endorse each member of the standing list of external reviewers.
- xii. External reviewer submits comments to the Chairperson and REC Secretariat and may be required to attend the meeting to discuss the protocol they review.
- xiii. Presentation of the external reviewer's comments should be led by the REC Chairperson.
- xiv. An external reviewer's report will be filed in the research protocol proposal file maintained by the REC Secretariat.
- xv. An external reviewer is not a voting member of the Committee.

SOP NO.7: Standard Operating Procedure for Expedited Review

1. Purpose

This SOP describes the approval process of studies with minimal risk; minimal risk changes or modifications/amendments required by LUANAR-REC; or minimal risk investigator-initiated clarifications, modifications/amendments to a previously approved protocol, and related documents to prevent unnecessary delays in reviewing them. The SOP also describes the approval process for studies by researchers and students so long as such studies are of minimal risk.

2. Scope

Expedited review applies to proposals, letters of clarification, letters of amendment, informed consent forms, and community awareness materials. The SOP applies to REC members, the Chairperson, and the secretariat.

It is the responsibility of the REC secretariat to determine which proposals should be reviewed and approved through an expedited process as long as such determination is within the standards described under the purpose section above.

3. Allowable Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedure

- i. Following the administrative screening as per **SOP NO. 5**, the secretariat and chairperson shall appoint three reviewers to undertake the expedited review
- ii. The reviewers shall independently review the submitted proposal and/or materials described under the scope section above.
- iii. In case of a proposal, the reviewers shall assess the protocol by using the **Proposal Assessment Form (002)** and send the completed forms and their recommendations to the secretariat within **Seven (7) days**.
- iv. In case of a proposal, the expedited committee shall meet within **Seven (7) days** after the secretariate receiving all the assessment forms.
- v. In case of review of other materials (not full proposals), reviewers shall review them and send their written opinion/recommendations to the secretariat within **Seven (7) days**.
- vi. The Chairperson and secretariat shall confer to make a decision based on the recommendations from the reviewers. If one reviewer expresses a strong deferring opinion, the proposal review would be referred to the full Review Committee and a decision would be made based on **SOP NO. 4**.
- vii. The Secretariat shall communicate in writing the decision of the expedited review **Seven (7) days** after the decision has been made.
- viii. The chairperson shall report to the Review Committee for ratification of the decision made on its behalf at the next full committee meeting.

Definition of Terms

Expedited review: A speedy review process for proposals of minimal risk including those of students and of minor changes to the originally approved proposals with minimal risk in nature and/or for minor requests.

Expedited approval: REC approval, granted by the chairperson of REC, together with the secretariat, based on the reviews and recommendations of two or three reviewers of a protocol of minimal risk or of minor changes to the previously approved research studies of minimal risk.

Minimal risk: Risk that entails a situation where the probability and magnitude of harm or discomfort anticipated in the research are not greater than that which is ordinarily encountered in daily life (i.e. probability and magnitude of harm or discomfort that is not anticipated to affect the safety, physical or mental integrity of the study participants).

SOP NO.8: Standard Operating Procedure for Management of Protocol Amendments

1. Purpose

This SOP describes how protocol amendments are managed and reviewed by REC.

2. Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by REC. Amendments made to protocols cannot be implemented until they are reviewed and approved by REC.

3. Allowable Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedure

- i. The Secretariat receives the amended protocol together with an application for review of amendments on the **REC Form for Request of Protocol Amendment (Form 004)**.
- ii. For minimal risk amendments, an expedited review process shall apply as per **SOP NO. 7**
- iii. For protocols with major amendments, the standard review process as per **SOP NO. 4** shall apply.
- iv. The Secretariat shall communicate the decision of review to the investigator in accordance with the chosen review procedure of either **SOP NO. 4** or **SOP NO. 7**
- v. REC requires that an amended protocol must highlight all the specific amendments in the amended protocol for ease of reference.

Definition of Terms

Protocol amendment: A change to the study protocol during the planning or course of study.

Major amendments: These are protocol changes that affect the safety and physical or mental integrity of the study participants. Examples of these include:

- a. Changes in the purpose/objectives or design of the study;
- b. Changes in the study procedures;
- c. Changes in the study population (sample size, age range, inclusion and exclusion criteria, study sites/places);
- d. Changes in the PI are to be accompanied by the CV of the new PI.

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 <hr/>
Principal Investigator Name <hr/>		Contact Person (if other than PI) <hr/>
Phone: _____		Phone: _____
Email: _____		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;

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

Signature of Principal Investigator

Date

Approval of Changes/Modifications by LUANAR-REC

Chairperson Recommendation: _____

Chairperson Signature: _____

LUANAR-REC Office Use only:

Approval

Date: _____

Approved by:

SOP NO.9: Standard Operating Procedure for Annual Continuing Review

1. Purpose

This procedure describes how annual continuing reviews of protocols are managed by LUANAR-REC.

2. Scope

This SOP applies to conducting of continuing review of study protocol involving human participants or animal subjects at intervals appropriate to the degree of risk but not less than once per year. The purpose of the annual continuing review is to monitor the progress of the entire study, not just changes in it, to ensure the continued protection of the rights and welfare of research participants. Continuing review of a study may not be conducted through an expedited review procedure, unless;

- a. the study was eligible for and initially reviewed by an expedited review procedure; or
- b. the study has changed such that the only activities remaining are eligible for expedited review.

3. Allowable Exceptions

This SOP should be followed without deviation.

4. Procedures

- i. LUANAR-REC approval is valid for a maximum period of 12 months. Therefore, all approved protocols shall apply for continual review every 12 months.
- ii. The Secretariat shall remind investigators in writing at least one month before the due date for continuing review applications.
- iii. All approved studies must submit a progress report with the application for continuing review using the LUANAR-REC **Continuing Review Form (Form 005 and Form 006)**.
- iv. Upon receipt of the application package, the LUANAR-REC secretariat performs an administrative review.
- v. Applications go through the standard review process.
- vi. The Chairperson of REC signs and dates the Continuing Review Application Form after a decision has been reached.
- vii. The completed Continuing Review Form is the official record of the decision reached by REC for the protocol.
- viii. The Secretariat shall communicate the decision to the investigator within **Seven (7) days** by sending a copy of the completed approval letter.

Definition of Terms

Approved protocols: Protocols that have been *approved without stipulations* or *approved with recommendations* by REC may proceed. Protocols that have been *approved with stipulations* by the

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

REC may not proceed until the conditions set by the REC in the decision have been met. Protocols should be amended and submitted to the REC within *one* month for re-review.

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.

I. 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	

2. PROJECT FUNDING	
Funding Sources:	(1) Agency/Company Name
	(2) Agency/Company Name
	(3) Agency/Company Name

3. RESEARCH OR PROJECT SITE (S)
<p>List all performance sites for this study (including names of foreign countries with sites)</p>

4. 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

5. INTERVENTION INFORMATION

Intervention

- ☐ Survey questionnaire ☐ Experimental Protocol ☐ Drug

- | | | |
|--|--|--|
| | | |
|--|--|--|

- ☐
- Other, briefly explain.

6. PROGRESS REPORT

I. Enrolment and demographic information: **LEAVE NO LINE BLANK**

i. The total number of participants requested in the original LUANAR-REC application

ii. Number of participants enrolled since the last progress report

iii. 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 _____

(2) Withdrawn from study _____

(3) Deaths related to study _____

(4) Deaths unrelated study _____

(5) 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?

3. 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;

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

Signature of Principal Investigator

Date

THIS SECTION IS FOR LUANAR-REC USE ONLY

Comments:

Decision: _____

LUANAR-REC Office Use only:

Approval
Date: _____

Approved by: _____

Chairperson's Signature: _____ **Date:** _____

LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)

LUANAR-REC FORM 006: Application Enclosures Checklist for Continuing Review

LUANAR-REC Protocol Number as assigned: _____

Research or Project Title

Name of Principal Investigator: _____

Check all that are included in your submission for continuing review.

The following must be included in the submission for continuing review:

- ☐ Continuing Review Application, complete with the signature of PI.
- ☐ Progress Report, attached to the application.

Include the following only if applicable:

- ☐ A current copy of the Consent Form(s) stamped with an approval date.
- ☐ A clean copy of the Consent Form(s) with revisions if necessary (for new approval stamp) consent form.
- ☐ Adverse Event Summary Table, if applicable.
- ☐ Current Approval letters from other foreign sites with REC/Institutional Review Board (IRB)
- ☐ The complete protocol including modifications previously approved by REC (if submitting an amendment or modification to the original protocol).
- ☐ Recruitment Information (Adds, Web postings and letters if modified from originally approved recruitment materials and if applicable).
- ☐ Additional information PI considers important for review by REC.

SOP NO.10: Standard Operating Procedure for Declaring Conflict of Interest

1. Purpose

This SOP explains the procedure for declaring a conflict of interest by LUANAR-REC members, the secretariat, and external reviewers.

2. Scope

This SOP applies to REC members and the secretariat in managing a conflict of interest.

3. Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedure

- i. REC secretariate shall inform and organise training for members, secretariat, and reviewers on issues of conflict of interests;
- ii. REC members, assigned external reviewers who are not necessarily REC members, and the secretariat shall declare a conflict of interests and sign a conflict of interest declaration form in respect of a protocol in which there is a conflict of interest;
- iii. In the case of a REC member or member of the secretariat being in a position deemed to compromise the professional ability of the member or secretariat, such a member shall be required to declare the state and situation of his/her compromised position to the Chairperson of REC;
- iv. An individual who has declared a conflict of interests and/or a compromised position shall recuse oneself from deliberations and decision-making on the particular protocol;
- v. The declaration of a conflict of interests shall be minuted and properly recorded including the time of recusal and re-joining the meeting;
- vi. Where it transpires that an individual failed to declare a conflict of interest with regard to a particular study, REC shall take appropriate actions including a hearing.

Definition of Terms and Some Situations of Conflict of Interests

Conflict of Interest (COI):

- i. A conflict between the personal interests and official responsibilities of a person in a position of trust.
- ii. A conflict of interest may arise when a member holds interests with respect to a specific protocol for review that may jeopardize his/her/their ability or judgment to provide a free and independent professional review/evaluation of a given research protocol.
- iii. A COI may arise when a member has personal financial, material, or social ties in the proposed research study whose protocol is under review.

LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)

LUANAR-REC FORM 007: Conflict of Interest Declaration Form

Name (the one in conflict)	
Proposal Title	
LUANAR-REC Protocol Number as assigned	
Principal Investigator	
Co-investigators	
Describe the type of conflict of interest	
REC Secretariat: Describe the action taken to avoid a conflict of interest	

Signature

Date

SOP NO.11: Standard Operating Procedure for Inspection and Monitoring of Approved Protocols

1. Purpose

This SOP explains how monitoring/inspection of approved studies will be conducted.

2. Scope

The usage of this SOP applies to LUANAR-REC members, secretariat, investigators, and study staff.

3. Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedures

- i. LUANAR-REC shall inspect/monitor approved studies through the following mechanisms;
 - Progress report submitted within three months of approval of the study and annual report for medium to long term studies.
 - The final reports are submitted at the end of the study.
 - Inspection reports by REC-appointed sub-committee.
 - Where possible, copies of publications at the end of the study
- ii. Normally, inspection visits will be arranged in advance with the Principal Investigator, but REC may also conduct unannounced visits.
- iii. The Principal Investigator shall submit periodic progress reports on the study as prescribed by the clearance letter.
- iv. The REC inspections sub-committee shall submit an inspection report to the review committee.
- v. REC shall review the reports and make recommendations through either expedited or convened full committee review process.
- vi. The Chairperson and secretariat shall communicate recommendations/feedback on reviewed reports to the investigator.

Definition of Terms

Inspection: An action that REC or its sub-committee or its representatives visit the study sites to assess how well the investigators are complying with the approved protocol and applicable regulatory requirements.

LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)

LUANAR-REC FORM 008: Inspection and Monitoring of Approved Protocols Form

1.0 Title of the Approved Study

2.0 LUANAR-REC Protocol Number as assigned

3.0 Name of the Principal Investigator(s)

3.1 Address

Physical Address:

Email:

Phone Number:

3.2 Collaborator(s)

(1)

(2)

(3)

(4)

4.0 Objectives of the Study

(1)

(2)

(3)

(4)

(5)

5.0 Study Site (s) _____

6.0 Evidence of Approval of the Study (*Attach the REC Approval Letter*)

7.0 Commencement Date of the Study _____

8.0 Status of the Study (i.e. On-going or Completed) _____

If completed, skip question 9 and 10

9.0 If on-going, record what has been done so far up to this stage.

I 0.0 Plan of Next Activities

I 1.0 Operational problems being faced by researchers and suggested solutions.

I 2.0 If possible, conduct a general brief interview with some research participants to learn their experiences in the participation of this study and record such experiences below (These could be either positive or negative experiences).

13.0 Inspector's Judgement Regarding:

- a. Researcher's Adherence to the Study Objectives and Methodology
- b. Researcher's Adherence to the Observance of the Ethical Issues (i.e. rights, consent, confidentiality, privacy, safety/wellbeing of participants etc). Examine documentation on the study file with a proper focus on the administered consent form if it is in line with what was approved by REC.
- c. The Status of the Available Research Facilities for the Proper Implementation of the Approved Study (i.e. equipment, personnel etc).
- d. The Degree of Participation/Involvement of the Collaborators as indicated in the approved protocol.
- e. Data management and storage of after the study period for a maximum of three years

I 4.0 Inspector's General Comments/Observations/Recommendations.

Name of Inspector: _____

Signature: _____

Date: _____

SOP NO.12: Standard Operating Procedure for Managing Non-Compliance by Investigators

1. Purpose

This SOP explains how LUANAR-REC will handle non-compliance by investigators and research team members as per the guidelines.

2. Scope

This SOP applies to

- All research approved by LUANAR-REC
- LUANAR-REC secretariat, members, and expert reviewers
- Research investigators

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- i. Non-compliance can be identified through LUANAR-REC monitoring, reports, and whistle-blowers.
- ii. When non-compliance is suspected, the secretariat conducts investigations to verify/clarify the non-compliance where necessary.
- iii. Where non-compliance is confirmed, the Secretariate makes appropriate recommendations to the investigator.
- iv. The Secretariate reports at the next full committee meeting of LUANAR-REC for review and decisions.
- v. REC meeting decides on the course of action, which may include:
 - advising investigators on what action to take to address the non-adherence;
 - depending on the gravity of the non-adherence LUANAR-REC should suspend or terminate approval of current studies;
 - refuse subsequent applications from the investigators if there are repeated cases;
- vi. Communicate the decision to the investigator;
- vii. Follow up to verify whether the decision is being implemented.

Definition of Terms

Compliance: Adherence to LUANAR-REC Guidelines and applicable national guidelines and regulatory requirements.

SOP NO.13: Standard Operating Procedure for Premature Termination of Protocols

5. Purpose

This SOP describes how protocol termination is managed by REC. Protocols can be terminated at the request of the Principal Investigator when subject enrolment and subject follow-up are discontinued or after a decision by LUANAR-REC.

6. Scope

This SOP applies to all studies approved by REC. Premature termination may be requested by the Investigator, or recommended by REC or other regulatory agencies. Reasons for termination include ethical and scientific misconduct, safety, financial, new information/knowledge, and efficacy (stopping rules).

7. Allowable Exceptions

This SOP must be followed without deviation.

8. Procedures

- viii. For REC-initiated premature termination, the investigator submits the completed LUANAR-REC FORM 008: Inspection and Monitoring of Approved Protocols Form
- ix. For Principal Investigator-initiated premature termination, the investigator submits completed LUANAR-REC FORM 009: Termination Notification Form.
- x. The Secretariat reviews the form for completeness of the information and refers it to the chairperson.
- xi. At the next full committee meeting, the chairperson presents the case for review recommendations regarding the termination.
- xii. The Secretariat communicates to the investigator the recommendations to be fulfilled to prematurely terminate the study.
- xiii. The Secretariat must report the termination at the next REC meeting.

Definition of Terms

Termination: The act of bringing to an end the study protocol.

LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)

LUANAR-REC FORM 009: Termination Notification Form

PROTOCOL TITLE			
LUANAR-REC Protocol Number as assigned			
PRINCIPAL INVESTIGATOR			
LUANAR-REC APPROVAL DATE		DATE OF LAST REPORT	
STARTING DATE		TERMINATION DATE	
NO. OF SUBJECTS		NO. ENROLLED	
SUMMARY OF RESULT			
REASON FOR TERMINATION			
APPLICANT NAME			
DATE			

Note: The committee may request additional information to support this request/notification.

SOP NO.14: Standard Operating Procedure on Payment of Fees in Respect of the Review and or Approval of a Research Protocol

1. Purpose

This SOP explains a policy requirement for the payment of required fees for the provision of a service by LUANAR through LUANAR-REC.

2. Scope

The SOP stipulates the actual fee amount required to be paid by any researcher (whether an individual or an organization) that intends to conduct research in Malawi whereas the proposed or intended research is to be reviewed and/or approved by LUANAR-REC. The determined fee as indicated below is paid in two parts;

Part One:

- Application/processing fee of **US\$ 150 or its MKW** equivalent for all study protocols submitted by staff, faculty members, post-graduate students or any other collaborating partner.
- Application/processing fee of **US\$ 10 or its MKW** equivalent for all study protocols submitted by undergraduate students at LUANAR.

Part Two:

A research compliance and capacity building fee of **10% of a research protocol budget as described in a specific study protocol** submitted by staff, faculty members, post-graduate students or any other collaborating partner when the REC approves the study. **Undergraduate students are expected from paying the 10% compliance and capacity building fee.**

The money realized from these fees is to be used for the day-to-day operations of REC to perform the following research and ethics compliance-related functions;

- Proposal review meetings of REC
- Inspection, compliance, and monitoring of research studies to promote the protection of research subjects in the field
- Promoting capacity building for research within LUANAR
- Supporting continuing education for members of REC on research ethics and integrity
- Organizing research dissemination conferences as a platform for offering feedback to the communities
- Student research grants to encourage young researchers

The usage of this SOP applies to researchers/investigators and their collaborators; REC members; REC secretariat; LUANAR Faculty members and their collaborators and students. REC reserves

the right to review the fees through a recommendation to the Director of Research and Outreach at LUANAR.

3. Exceptions

This SOP is meant to be followed without deviation.

4. Specific Procedure

- i. Investigators/researchers shall submit an application package of a protocol and a duly completed checklist for review by REC.
- ii. On submission of an application package, the researcher or the researcher's authorized representative pays to the LUANAR Bank Details as advised by the secretariat, the stipulated application/processing fee of US\$150 or US\$10 or its MKW equivalent as stipulated above in order for the application package to be accepted and recorded on the register and log for review.
- iii. On receipt of proof of payment, the REC secretariat shall screen the completeness of the application package.
- iv. If satisfied, REC shall determine an ethical approval of an intended research study.
- v. After ethical approval, the REC secretariat notifies the researcher/investigator or the authorized representative to make arrangements for payment of the required fee of **10% of the research budget** to the LUANAR Bank Details as advised by the secretariat, as indicated in the protocol of the research study that has been reviewed.
- vi. On receipt of proof of payment, the REC Chairperson through the secretariate issues written ethical approval, being a permit to conduct/implement the intended research study.
- vii. Implementation of the approved research study shall commence only after the REC has issued the permit.

SOP NO.15: Standard Operating Procedure for Storage of Active Files

1. Purpose

This SOP describes how documents of active protocols or studies approved by LUANAR-REC are stored.

2. Scope

This SOP applies to the LUANAR-REC Secretariat and its Members.

3. Allowable Exceptions

The SOP must be followed without deviation.

4. Procedures

- i. File protocols and related documents for each approved active study in one file using an online platform. The documents to be filed include:
 - Original application documents and any updates received during the study.
 - Investigator's brochure of similar documents.
 - Approval letters and other correspondence sent to the investigator.
 - Approved documents (protocol, protocol amendments, informed consent, information provided to participants and advertising materials).
 - Adverse events report or safety report received.
 - Progress and monitoring report.
 - Continuing review reports.
- ii. Assign the active study files with unique identifiers.
- iii. Maintain an online study files in a secure way until the final report is reviewed and accepted by the committee.
- iv. All administrative documents will be in a separate file managed by the REC Secretariate

Definition of Terms

Active Study Files: Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by REC.

Administrative documents: Documents include official minutes of Committee meetings and any other official REC documents.

SOP NO.16: Standard Operating Procedure for Convening an Extra-ordinary meeting

3. Purpose

The purpose of this procedure is to describe how LUANAR-REC convenes extra-ordinary meetings.

3.1.3. Scope

- The extra-ordinary meeting can be convened for the following reasons:
 - i. Urgent issues, which if delayed will affect or have an impact on the public benefit or national interest.
 - ii. The unusually high number of deaths reported in a study.
 - iii. Other appropriate reasons as reviewed by the Chairperson.
- LUANAR-REC Secretariat and members

3.1.4. Allowable Exceptions

This SOP must be followed without deviation.

3.1.5. Procedures

- i. The Secretariat informs the Chairperson of the reported or identified situation requiring an extraordinary meeting.
- ii. The Chairperson assesses the need for the extraordinary meeting.
- iii. The Chairperson contacts all members for an extraordinary meeting.
- iv. The meeting should be convened within 48 hours of the notification.
- v. The meeting shall proceed if at least 4 members in addition to the chairperson or vice chairperson are present with the necessary expertise.
- vi. The meeting will be conducted as per the standard procedure for a regular meeting and representation in point (v) must be maintained throughout the entire discussion and voting portions of the meeting.
- vii. Decisions made at the extraordinary meeting may be effected immediately but shall be ratified at the next full meeting.

Definition of Terms

Extra-ordinary meeting: A committee meeting that is scheduled outside of a normally scheduled meeting to review study activities that require Full Committee review and approval.

SOP NO.17: Standard Operating Procedure for Management of Participant's Complaints

1. Purpose

This SOP describes how LUANAR-REC manages complaints from study participants.

2. Scope

This SOP applies to Study Participants, Investigators, REC secretariat and members.

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- i. The investigator provides participants with the contact information of REC as presented on the informed consent details.
- ii. Participants may contact the Chairperson of REC or the investigator.
- iii. The investigator addresses the complaint with the participant. If necessary, refer the matter to LUANAR-REC
- iv. The Chairperson may recommend further discussion with the investigator and participant.
- v. If necessary, the chairperson will refer the matter to a full REC meeting.
- vi. The Chairperson through the secretariate will give feedback to the participant and investigator on the outcome of the REC meeting.
- vii. A record of the complaint and resolution should be maintained in the appropriate file.

Definition of Terms

Complaint: Verbal and written communication from study participants to investigators, sponsors, and REC regarding the conduct of a study.

SOP NO.18: Standard Operating Procedure for Material Transfer Agreement

1. Purpose

The purpose of this procedure is to describe how to facilitate a Material Transfer Agreement (MTA) between LUANAR and collaborating institutions.

2. Scope

This SOP applies to

- i. LUANAR Management
- ii. Investigators
- iii. Collaborating Institutions
- iv. REC secretariat and members

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- i. The investigator indicates in the protocols any need for materials transfer.
- ii. The investigator completes the Materials Transfer Agreement (MTA) form and submits it together with other documents in the application package.
- iii. REC advises the secretariat to sign the MTA form.
- iv. Where an MTA form was not part of the application, REC advises the investigator to submit a completed form, which is then signed by the secretariat.
- v. A copy of the signed MTA is sent to the Investigator.
- vi. A copy of the signed MTA will be kept in an appropriate LUANAR-REC file.

Definition of Terms

Material Transfer Agreement (MTA): A legal document defining the conditions under which research or other materials can be transferred and used among research laboratories.

LUANAR RESEARCH ETHICS COMMITTEE (LUANAR-REC)

LUANAR-REC FORM 010: Material Transfer Agreement Form on Shipping of Samples

Samples collected from LUANAR for research purposes are the property of the Government of Malawi represented by the LUANAR, under the authority of REC. Such samples can be accessed or recalled by the Government of Malawi and LUANAR at any time without let or hindrance.

Shipment of samples outside the country without proper justified reasons is not allowed. Investigators are encouraged to develop the capacity for undertaking all the required experiments in the country. In special cases where this may not be possible, the investigators must justify in the proposal the reason for exporting samples.

In the review process, the following have to be considered:

- i. There must be a justification for the importation and exportation of samples.
- ii. REC shall make sure that there is a Material Transfer Agreement between relevant institutions in the context of the exportation and importation of samples. The Material Transfer Agreement shall include the following:
 - a. The intention of the importation and exportation
 - b. The duration of storage
 - c. Location of storage
 - d. The appropriate informed consent authorizing the exportation and importation
 - e. To whom it will be accessible
 - f. Who will be the controlling officer of the samples
 - g. Ownership of samples
 - h. Capacity building
- iii. For studies that require the shipping of samples, the MTA form at LUANAR-REC must be filled out. In case there are issues of Intellectual Property Rights (IPR), the committee shall advise the concerned parties to have a prior Agreement or IPR which has to be signed by all parties before REC approval.
- iv. Samples collected in Malawi will not be sold or commercialized in any form.
- v. Initial authorization to store samples can last up to 5 years, if one wishes to use the samples beyond 5 years, authorization must be sought from LUANAR-REC. This authorization will last another 5 years before it could be due for renewal.
- vi. Capacity building plan. Please note exportation of samples should be considered a last resort. Efforts to build local capacity and expertise should be a priority.

MATERIAL TRANSFER AGREEMENT FORM
LUANAR-REC Protocol Number as assigned:
Title of protocol/proposal
a) Intention and justification of transfer
b) Duration of Storage: Indicate the date, month or years
c) Responsible Party
d) Location of stored samples
e) Transportation of samples

f) Ownership of samples
g) After all laboratory testing has been completed: Describe what will happen to the samples
h) Appropriate informed consent authorizing the exportation and importation of samples
i) To whom will the samples be accessible
j) Who will be the controlling officers of the samples?

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

Signed by:

Name of the PI

Name of Co-PI (if applicable)

Name of Institution

Name of Institution

Signature

Signature

Date Signed

Date Signed

LUANAR-REC APPROVAL (For Official Use ONLY)

Name of the Chairperson

Name of LUANAR-REC Administrator

Signature

Signature

Date Signed

Date Signed

LUANAR-REC STAMP OF APPROVAL

LUANAR-REC Office Use only:

Approval

Date: _____

Approved by:

SOP NO.19: Standard Operating Procedure for Documentation of Meetings

1. Purpose

The purpose of this procedure is to describe the process of documentation, approval, circulation and archiving of minutes of LUANAR-REC meetings.

2. Scope

- This SOP applies to the REC secretariat and members.

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- i. The Secretariat documents the proceedings of the meeting from beginning to end and records the following:
 - a. Name of the person preparing the minutes
 - b. The location where the meeting is held (Venue, District)
 - c. Meeting date
 - d. Attending LUANAR-REC members and guests
 - e. Agenda items
 - f. The individual serving as Chairperson of the meeting
 - g. Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- ii. For each application being reviewed, record:
 - a. Sponsor name
 - b. Protocol number/date/version of the protocol, when available
 - c. Investigator name
 - d. Name of primary reviewer presenting the proposal and study materials
 - e. Discussion as deemed appropriate by the Chairperson
 - f. Number of members voting 'yes', 'no'
 - g. Number of abstentions
 - h. Reference to the investigator approval letter with committee recommendations
 - i. Determination of the next requested continuing review if applicable
- iii. For applications on expedited review, record:
 - a. Sponsor name
 - b. Protocol number
 - c. Investigator name
 - d. List of expedited approval requests and outcomes
 - e. Reference to the investigator approval letter with Chairperson recommendations
 - f. Determination of the next requested continuing review if applicable

LUANAR-REC GUIDELINES AND SOPS VERSION 2.0

- iv. For continuing review, record:
 - a. Sponsor name
 - b. Protocol number
 - c. Investigator name
 - d. Indication of the Committee's recommendations to continue, terminate or amend the study
- v. For a review of adverse event notification and final report, record:
 - a. Sponsor name
 - b. Protocol number
 - c. Investigator name
 - d. Actions deemed appropriate by the Committee review
- vi. For termination of approval, record:
 - a. Sponsor name
 - b. Protocol number
 - c. Investigator name, the reason for termination
- vii. Document decisions and outcomes in all meetings
- viii. Draft minutes and submit them to the Chairperson for approval
- ix. Chairperson signifies approval by signature and date
- x. Circulate approved minutes to LUANAR-REC members as part of materials for the next meeting
- xi. Adopt minutes at the next meeting
- xii. File minutes in the appropriate file

Definition of Terms

Agenda: A list of things done or discussed; program of business at a meeting.

Minute: An official record of the business discussed and transacted at a meeting, conference, or workshop

SOP NO.20: Standard Operating Procedure for Audit of LUANAR-REC

1. Purpose

The purpose of this procedure is to guide LUANAR-REC on how to prepare for an audit.

2. Scope

This SOP applies to

- REC secretariat and members
- LUANAR management and staff
- Researchers and investigators

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- LUANAR Management can initiate the LUANAR-REC audit in writing to the REC chairperson.
- LUANAR Management can appoint internal or external individuals or firms to conduct the audit of LUANAR-REC.
- LUANAR-REC chairperson establishes contact with auditors to agree on a program for the audit.
- The Chairperson informs LUANAR-REC members and secretariat, and investigators where necessary.
- The Secretariat shall organise all the necessary files for the audit.
- The Secretariat must avail themselves for the meeting with auditors.
- The Secretariat must get a debrief from the auditors.
- The auditors shall send a report to the LUANAR Management.
- LUANAR Management shall discuss the report with the LUANAR-REC chairperson and agree on the course of action from the recommendations of the report.
- The Chairperson through the secretariat shares the audit report with members at the next full committee meeting.

Definition of Terms

Audit: A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted, and data were recorded and accurately reported according to the SOPs and applicable regulatory requirements as guided by NCST.

SOP NO.21: Standard Operating Procedure for Review of Guidelines and Procedures

1. Purpose

This SOP describes how to update REC guidelines and SOPs.

2. Scope

This SOP applies to

- REC secretariat and members
- LUANAR management and staff
- Researchers and investigators

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- LUANAR-REC shall annually assess the need to review guidelines and SOPs.
- LUANAR-REC shall review SOPs periodically or when a significant need arises.
- The review process shall be initiated at a full LUANAR-REC meeting.
- A sub-committee to conduct the review shall be appointed at the full meeting.
- LUANAR-REC shall submit revised guidelines and SOPs to LUANAR management for administrative approval and to NCST for regulatory approval and endorsement.
- LUANAR-REC shall ensure proper revision of guidelines and SOPs, in terms of:
 - Numbers of SOPs;
 - Assignment of version numbers and effective dates;
 - Changing the version number with only decimals if the revision is based on minor changes;
 - Major changes will require changing the version number;
 - After a change in the version, all old SOPs shall be retrieved from circulation;
 - One master copy will be maintained on the REC file;
 - Electronically circulated guidelines and SOPs shall be in PDF;
 - There shall be a hard copy version within 4 weeks from the effective date;
 - After approval of the guidelines and SOPs, the new version will be circulated based on a circulation list.

Definition of Terms

Guideline: Any suggestion and or rules intended as a guide for specific practice.

SOP NO.22: Standard Operating Procedure for Providing Feedback to Researchers Post-Ethics Review

1. Purpose

This SOP outlines the process for providing structured feedback to researchers following the review of their proposals by LUANAR-REC.

2. Scope

This SOP applies to

- REC secretariat and members
- Researchers and investigators

3. Allowable Exceptions

This SOP must be followed without deviation.

4. Procedures

- After the ethics review meeting, the REC Secretariat compiles all committee members' comments and recommendations.
- The REC Secretariat will send the researcher the feedback via official email within 7 working days after the review meeting.
- The feedback email should include:
 - A summary of the committee's decision (e.g., approval with conditions, resubmission required).
 - Detailed comments and recommendations.
 - Instructions on how to submit the revised proposal.
 - A timeline for addressing the comments
- Researchers will have a minimum of two weeks from the date they receive the feedback to address the committee's comments.
- If additional time is required, researchers must submit a written request for an extension, stating the reasons for their request.
- The REC will review and respond to the request within five (5) working days.
- The REC through the secretariate will send monthly reminders to the applicant within three (3) months.
- Researchers will have a maximum of three (3) months from the date they receive feedback for REC, beyond which they will need to make a new application.

Definition of Terms

Feedback: Any information provided as a result of the review process to an ethics applicant.