STANDARD OPERATING PROCEDURES OF THE MEDICAL RESEARCH ETHICS COMMITTEE, UNIVERSITI MALAYSIA SARAWAK

1. Objectives

This SOP serves as the organizational framework and describes the Terms of Reference (TOR), structure and composition of the Medical Research Ethics Committee (MREC) of Universiti Malaysia Sarawak (UNIMAS).

2. Scope

The Medical Research Ethics Committee, Universiti Malaysia Sarawak (MREC-UNIMAS) was established to review the ethics of medical and other health related research involving human participants conducted by UNIMAS. The main functions of this committee is to:

i. Approve, disprove or request for revision of research studies involving human subjects in order to ensure the protection of their dignity, rights, safety and well-being,
ii. Monitor and oversee conduct of study (if necessary),
iii. Suspend or terminate study.

3. Structure of the MREC

3.1 Appointment

The Deputy Vice Chancellor (Research & Innovation) appoints the Chair and committee members of the MREC to facilitate the discharge of its functions

3.2 Tenure of Membership

i. The tenure of membership shall be **two (2)** years with a renewal of every **two (2)** years. Once a nominated member has agreed to be part of MREC, an official appointment letter will be issued.
ii. There will be no limit to the number of times that membership can be renewed.

3.3. Appointment of New Members

New members will be appointed under the following circumstances.

i. When a regular member completes his tenure and does not wish to be renewed as member.
ii. If a regular member resigns.
iii. If a regular member fails to perform his responsibilities as described in his document, and as judged by the chairperson on specific grounds.

3.4. Composition of MREC

This committee will be an independent body constituted of medical, scientific and lay members from within and from outside of UNIMAS. The MREC is composed of the following members, being men and women, as depicted below:

i. Chairperson;
ii. Three members of the Faculty of Medicine & Health Sciences, UNIMAS;
iii. At least two members who are layperson, who have no affiliation with the institution, are not currently involved in medical or scientific work, and preferably from the community in which the institution is located;
iv. At least one member with knowledge of, and current experience in the professional care, counselling or treatment of people (e.g medical practitioner, social worker, psychologist nurse, as appropriate);
v. At least one member who is a lawyer.

3.5 Responsibilities of the Committee

i. The committee's primary responsibility will be the protection of dignity, safety, rights and confidentiality of the research subjects.
ii. The committee shall uphold the sponsor's right to confidentiality of proprietary information.
iii. The committee shall review all research proposals submitted within specified time limits.
iv. The committee shall maintain concise but clear documentation of its views on the research proposal.
v. The committee shall review the progress of each research project at appropriate and specified intervals, but not less than once a year.
vi. The committee shall review the qualifications of all investigators participating in the proposed research study.

4. Function of Members

4.1. Chairperson

i. The Chairperson is appointed for his or her ability to draw on the experience of all members. He/She is also responsible for managing the agenda and ensuring that all relevant items are covered and adequately recorded.
ii. The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
iii. The Chairperson will preside over all elections and administrative matters pertinent to the committee's functions.
iv. In case of anticipated absence, the Chairperson will nominate among the committee member an Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.
v. When required, the Chair may invite special attendees from relevant specialised areas to the scheduled meetings, that may include but not limited to the need for:
    - Additional scientific, clinical or scholarly expertise.

- Particular knowledge about potentially vulnerable populations
- Broader understanding of gender or cultural issues.

4.2. Laymembers

The qualifications of lay members are their independence from the institution and their non-involvement in medical, scientific or legal work. The lay members who are recruited from the community where the institution is located are more likely to understand the said community and how its member would view involvement in research. Lay members who have no experience in professions associated with research in human subjects are more likely to bring a truly lay perspective.

*Honorarium is paid to members from **outside the institution** for attendance in each meeting.

5. The Secretariat

The Secretariat is appointed by the Dean of the Faculty of Medicine and Health Sciences, UNIMAS. The Secretariat, in consultation with the chairperson will be responsible for the following functions:

i. Receiving all research proposals for the Committee.
ii. Forwarding all materials for review by committee members.
iii. Preparation and dissemination of agenda for all committee meetings.
iv. Notification of review outcome of research proposals.
v. Preparation and circulation of minutes.

Retention and safekeeping of all records and documentations.

6. Functions and Operations

6.1. Meetings

i. The committee will hold regular meetings at least once in four months. When there are no research proposals to review, the meetings may be held less frequently, but not less than once every six months.

ii. All regular members will receive notification of meeting schedules at one (1) week in advance.

iii. Agenda and documents to be discussed during the meeting will be circulated to the members at least a week before every scheduled meeting.

iv. Meetings will be held as scheduled provided there is a quorum. A quorum will be defined as one-half of the current regular members of the committee, rounded off to the next higher whole number.

6.2.Hierarchy

i. The Chairperson will be the head of the committee.

ii. The Secretariat will be the guardian of all documents and funds (if available) in the committee's possession.

iii. All other members will be regular committee members with equal ranking.

6.3. Minutes

i. The proceedings of all meetings will be recorded in Bahasa Malaysia or English and in form of minutes.

ii. The Secretariat will be responsible for coordination, recording and circulation of the meeting minutes.

6.4. Procedures

i. This committee will follow standards of as stated in Malaysian Guidelines for Good Clinical Practices (3rd Edition). The committee shall reserve the right to withhold favorable opinion/approval on a research proposal when the committee does not have reasonable assurance that the investigator(s) is qualified, and / or the site facilities are adequate, for the conduct of the study.

ii. All communication with the committee will be in writing.

iii. Before receiving the review materials, each committee will sign a Confidentiality Agreement to maintain the confidentiality of the review material and committee records. A copy of this agreement will be filed with the official records of the committee, and another copy with the sponsor.

iv. The committee will require the submission of eight (8) copies each of the documents listed in section 6.5 for every research proposal.

6.5. Documents for submission

The documents required for submission (where applicable) are the following:

i. Study proposal (a covering letter explaining the objective of the study, list of study centers (if multicenter) and the number of subjects to be evaluated at each center (if multicenter)

ii. Protocol and any amendments to it.

iii. Written informed consent form (ICF), including any amendments and its translation(s) into regional language(s).

iv. Written information to be provided to the subjects (e.g. patient information sheets (PIS), if applicable

v. Investigator's Brochure (IB)

vi. Subject recruitment procedures (e.g. advertisements), if applicable

vii. Available safety information

viii. Information about payments and compensation available to the subjects.

ix. Investigator's current curriculum vitae

6.6. Majority Vote

i. A majority vote for approval, disapproval, request for modifications or information, suspension or termination of the research proposal or ongoing study will be defined as one-half of the members in attendance at the review, rounded to the next whole number, provided:
    - A quorum is present as defined in section 6.4 (iv) and
    - The required membership composition described under section 3.3 is present.

ii. All voting members present at the review will vote on the research proposal. Voting by proxy by absent member/s is not permitted.

iii. Any member(s) of the committee who is/are participating in the research project under discussion will/have to opt out from all deliberations on the project. No one may vote on a protocol in which he or she is listed as an investigator/sub-investigator. This will be recorded in the minutes of the meeting. However, the investigator/sub-investigator may be called in to provide clarifications on the study protocol.

7. Review of protocol

7.1 Review Outcome:

The committee will document its view on the following:

- Approval
- Request for modification or information
- Disapproval
- Termination/suspension of the research proposal/ongoing study

7.2. Notification of Review Outcome

The outcome of committee's review will be recorded in writing within **one (1)** week of the date of review and conveyed to the investigator within a further week.

7.3. Procedures for Appeal for research proposals rejected by the committee

The applicant may appeal for a repeat review in writing, within **eight (8) weeks** of the receipt of the committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the committee, In such appeal cases, the committee will consider inviting independent experts in the relevant field as special invitees who will give additional assessment of the research proposal.

7.4. Review of Amendments to the Approved Research Proposal

i. All amendments to the approved research proposal shall be submitted to the committee immediately for its review.

ii. No changes in the protocol and/or ICF shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject, or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of monitor(s), telephone number(s)].

iii. The committee may use expedited review procedure in case of minor changes in the previously approved research. The expedited review may also be used when the amendments appear to involve no more than minimal risk to the study subjects.

iv. Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designated by the chairperson from among the members of the committee who reviewed the proposal. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.

v. A research activity may be disapproved only after review in accordance with non-expedited review procedure as mentioned in item (iii) above. The committee will adopt a method of keeping all members of the committee informed of these approvals under the expedited review procedure.

vi. Only the Chairperson shall make the decision to allow an expedited review as described in items (iii, iv & v) above.

7.5 Review of Advertisements for Patient Recruitment

All advertisements shall be reviewed and approved by the committee prior to their implementation in the study.

7.6. Review of On-going Studies

The committee will conduct continuing review of each on-going study by obtaining the status report from the sponsor/investigator at intervals appropriate to the degree of risk to the human subjects, but at least once a year. The investigator will promptly report the following to the committee:

i. Deviations from or changes to the protocol to avoid immediate hazards to the research/trial subjects.

ii. Changes increasing the risk to subjects and/or affecting significantly the conduct of the research/trial.

iii. All adverse drug reactions (ADRs) both serious and unexpected will be reported to the MREC-UNIMAS.

iv. New information that may affect adversely the safety of the subjects or the conduct of the research/trial.

8. Report Required of Research Sponsors

The research sponsor shall submit the following reports to the committee:

i. Annual Progress Reports The first report shall be submitted within thirty (30) days of completion of the year following the date of the first approval. Subsequent reports will be submitted at one- year intervals following the first report.

ii. In addition, the investigator should also promptly report the following to the committee:

- Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects.
- Changes increasing the risk to subjects and/or affecting significantly the trial.
- All adverse drug reactions (ADRs) that are both serious and unexpected.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

9. On-going Training of Members

i. The Chairperson will identify the training requirements of the committee members.

ii. The type of programs, areas for training and mentors for these workshops/training programs will be decided by the committee members at a scheduled meeting.

10. Records Retention

The committee will retain the following records for a period of at least three (3) years after the completion of a study:

i. Standard operating procedures (SOPs) effect at the time of review

ii. Membership list at the time of review

iii. Occupation/affiliations of the members at the time of review

iv. All documents pertinent to the research proposal

v. Minutes of meetings and,

vi. All correspondence with the research sponsor

These records will be made available to relevant statutory authority upon request.

11. Report to the Relevant Regulatory Authorities

The committee will make a yearly activity report for submission to the relevant regulatory authorities, which would include the following elements:

i. A quantitative evaluation of the activities of the committee

ii. The list of the proposals reviewed

iii. Status of each study proposal

12. Location and business Address

The location and business address of the committee will be decided by the Chairperson and the Member Secretary. A record of it will accompany these Standard Operating Procedures as a separate document. The current address is:

Medical Research Ethics Committee UNIMAS

Faculty of Medicine & Health Sciences
Universiti Malaysia Sarawak
94300, Kota Samarahan,
SARAWAK.

13. Amendments to the Standard Operating Procedures

Amendments to the Standard Operating Procedures of the MREC-UNIMAS shall be proposed in writing.

References

1. Ministry of Health Malaysia (2011). Malaysian Guidelines for Good Clinical Practice, 3rd Edition.
2. World Health Organization (2000). Operational Guidelines for Ethics Committees reviewing Biomedical Research.