

**UNIVERSITY OF MALAYA MEDICAL CENTRE
MEDICAL RESEARCH ETHICS COMMITTEE
SOP I: COMPOSITION**

1.0 PURPOSE

- 1.1 This SOP provides the organizational framework for the structure and composition of the Medical Research Ethics Committee (MREC) of the University of Malaya Medical Centre (UMMC).
- 1.2 This SOP also describes and provides the procedures, templates and forms that are related to nomination, appointment, privacy and confidentiality, training, and compensation of the UMMC-MREC and identifies who should read, agree to, sign, and date these documents.

2.0 SCOPE

- 2.1 This SOP applies to the formation and composition of the UMMC-MREC and its subcommittees which will carry out the task of providing an independent review of medical research protocols involving human participants that are conducted using the name of the Faculty of Medicine, University of Malaya (FOM-UM) or UMMC. These include studies submitted to the UMMC-MREC by:
 - i. FOM-UM staff and students,
 - ii. UMMC staff and students,
 - iii. UM staff and students who are not from FOM-UM,
 - iv. Non-UM/UMMC Principal Investigators (PIs).
- 2.2 Protocols that involve human subjects but are not medical/health-related studies are referred to the University of Malaya Research Ethics Committee (UMREC). Protocols involving non-human living vertebrates are referred to the Animal Care Committee of the Faculty of Medicine, UM.
- 2.3 This SOP describes the ethical values on which the UMMC-MREC is based; the composition and appointment of UMMC-MREC and its subcommittees and secretariat; their duties and responsibilities; and attendance, training, expected deliverables, and disclosure of conflict of interest.

3.0 RESPONSIBILITY

- 3.1 It is the responsibility of the Chair of the Board of Management (BOM) of UMMC to:
 - i. establish the UMMC-MREC.
 - ii. appoint the Chair and Members of UMMC-MREC.
 - iii. provide the terms of reference for these appointments in accordance with prevailing UMMC and UM policies, guidelines, and regulations.
- 3.2 The UMMC Director is responsible for appointing the UMMC-MREC Secretariat Staff.

- 3.3 It is the responsibility of the Chair and members of UMMC-MREC and its subcommittees and the secretariat staff to study, comprehend, comply with, and respect the procedures and guidelines set by the UMMC-MREC as approved by appropriate UMMC officials.
- 3.4 It is the responsibility of all newly appointed UMMC-MREC and subcommittee members to read, understand, accept, and sign appointment documents at the start of their appointment or reappointment to the UMMC-MREC.
- 3.5 It is the responsibility of new UMMC-MREC members to undergo training as early as possible during the course of his appointment and existing UMMC-MREC members to continuously update themselves and undertake training on relevant knowledge and skills. The UMMC-MREC Chair and Deputy Chair shall join UMMC-MREC members to attend training/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore, UMMC is responsible for providing support and an annual budget for specific training and other educational activities for UMMC-MREC members.

4.0 STRUCTURE AND FUNCTIONS

4.1 Organizational Structure of the UMMC-MREC

- 4.1.1 The Chair of the BOM-UMMC appoints the Chair and Deputy-Chair of MREC-UMMC upon the advice of the Dean of the Faculty of Medicine, UM or Representatives of Departments, FOM/UMMC along the line of authority indicated by the following chart.
- 4.1.2 The UMMC-MREC is established by authorization of the BOM-UMMC and exercises its mandate through the following structure:
- i. The Chair, BOM-UMMC, as the appointing officer.
 - ii. The Dean, Faculty of Medicine, UM or Heads of Departments as the recommending officers, as the case may be.
 - iii. The UMMC-MREC, as the implementing office.
- 4.1.3 Only the Chair, BOM-UMMC, has the authority to dissolve the UMMC-MREC after due process.

4.2 Composition of UMMC-MREC

- 4.2.1 The UMMC-MREC is composed of a minimum of the following members:
- a. Chair (A clinical academic staff appointed on advice of the Dean, Faculty of Medicine, UM).
 - b. Deputy Chair (A clinical academic staff appointed on advice of the Dean, Faculty of Medicine, UM).
 - c. Director of UMMC or named representative.

- d. A clinical academic staff from the Department of Medicine, FOM-UM, nominated by the Head of Department.
- e. A clinical academic staff from the Department of Surgery, FOM-UM, nominated by the Head of Department.
- f. A clinical academic staff from the Department of Psychological Medicine, FOM-UM, nominated by the Head of Department.
- g. A clinical academic staff from the Department of Paediatrics, FOM-UM, nominated by the Head of Department.
- h. An academic staff from the Department of Pharmacology, FOM-UM or from the Department of Pharmacy, FOM-UM (the term of appointment to be in rotation) nominated by the respective Heads of Department.
- i. Head, Department of Pharmacy, UMMC or named representative.
- j. Dean, Faculty of Law, UM or named representative.
- k. Lay member (at least two, of whom at least one shall not be qualified in the life sciences) nominated by the Chair, UMMC-MREC.
- l. Statistician (at least one) nominated by the Chair, UMMC-MREC.
- m. Secretary (at least one) - an officer of UMMC, by appointment of the Director, UMMC.

- 4.2.2 The UMMC-MREC shall comprise of both genders, and a mixture of scientific and/or medical members and non-scientific members.
- 4.2.3 The quorum for the full Committee (board) meeting is five (5) voting members including at least one scientific/medical member, at least one non-institutional member and at least one lay member.
- 4.2.4 The member from the Faculty of Law and the lay members are considered non-institutional members.
- 4.2.5 Only MREC members, who are independent of the investigation and the sponsor of the study, may vote/provide a decision on a study related matter.
- 4.2.6 The Secretary may provide an opinion on a study related matter but shall be a non-voting member.
- 4.2.7 Approval will only be granted if the majority of voting members at the UMMC-MREC meeting approve the study, except when a decision is made on an expedited basis (See SOP II-6.2: Classification of review)
- 4.2.8 The UMMC-MREC reports its decisions to the BOM-UMMC but is independent in its decision-making.
- 4.2.9 The BOM-UMMC shall not approve any study that has been disapproved by UMMC-MREC.
- 4.2.10 The decisions of the UMMC- MREC are also informed to the Medical Advisory Committee (MAC) of UMMC.
- 4.2.11 The UMMC-MREC can recommend the appointment of new member(s) as and when the need arises.
- 4.2.12 UMMC-MREC members should be willing to publicize his/her full name, profession and affiliation.
- 4.2.13 UMMC-MREC members will be required to sign a confidentiality agreement.
- 4.2.14 UMMC-MREC members who are not staff of UMMC or UM shall be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined by the BOM-UMMC.

- 4.2.15 UMMC-MREC members are selected according to their personal capacities based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of UMMC-MREC.
- 4.2.16 The duration of membership will be two (2) years. Appointments may be renewed on the recommendation of the UMMC-MREC Chair and upon approval of the Chair, BOM-UMMC. The appointment of members should take into account the continuity and introduction of new members.
- 4.2.17 The UMMC-MREC may further be supported in its deliberations on specific protocols or requests for advice on specific ethical and/or technical issues by independent consultants (**see SOP I- 5.0 INDEPENDENT CONSULTANTS**).

4.3 Composition of Serious Adverse Events (SAE) Subcommittee

- 4.3.1 The UMMC-MREC Serious Adverse Events (SAE) Subcommittee will review all types of serious adverse events and recommend its decisions at a full meeting of the UMMC-MREC.
- 4.3.2 The UMMC-MREC Chair will appoint the Chair and Members of SAE Subcommittee, which will consist of at least three members who are not members of UMMC-MREC.

4.4 Composition of Site Visit (SV) Subcommittee

- 4.4.1 The UMMC-MREC Site Visit (SV) Subcommittee will review/evaluate and visit selected researcher(s) and the study sites for projects involving risks to participants and generate recommendations for the action of UMMC-MREC.
- 4.4.2 The UMMC-MREC Chair will appoint the Chair and Members of the SV Subcommittee, which will consist of at least three members who are not members of UMMC-MREC.

4.5 Resignation, disqualification and replacement of members

- 4.5.1 A member may resign his/her position by submitting a letter of resignation to the Chair, BOM-UMMC through the UMMC-MREC Chair.
- 4.5.2 A UMMC-MREC member may not be reappointed for non-compliance of duties and responsibilities stated here in.
- 4.5.3 UMMC-MREC members who have resigned and members who are not re-appointed will be replaced by new members upon recommendations/nominations as stated in item 4.2 and upon approval of the Chair of BOM-UMMC.

4.5.4 The duration of appointment, disqualification, resignation, and replacement of secretariat staff are decided by the Director of UMMC based on discussion with the Chair, UMMC-MREC.

4.6 General Duties and Responsibilities of UMMC-MREC and Subcommittee Members

4.6.1 UMMC-MREC and subcommittee members shall submit their signed and updated CURRICULUM VITAE which will be filed in the UMMC-MREC and Subcommittee Membership Files (contains CV, Terms of Reference, and copies of Training Certificates of each member).

4.6.2 UMMC-MREC members are required to sign UMMC-MREC forms – **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the UMMC-MREC in the course of its work.

4.6.3 UMMC-MREC members should be willing to publicize their full name, profession, and affiliation to the UMMC-MREC upon request.

4.6.4 UMMC-MREC members must commit to record any conflict of interest within or related to their duties in the UMMC-MREC.

4.7 General attributes of UMMC-MREC and Sub-committees members

4.7.1 Possess a comprehensive knowledge of national and international Research ethics and regulation, institutional policies and relevant legislation.

4.7.2 Respect diverse backgrounds, perspectives and sources of expertise, in particular the contributions of general public representatives.

4.7.3 Ability to function as a team particularly under stressful circumstances.

4.7.4 Promote the culture of respect within and outside the research community pertaining to the research ethics review processes.

4.7.5 Upholding the UMMC-MREC decisions even if these may not be popular with investigators, the research communities or University officials.

4.7.6 Ready to pursue continuing education in research ethics.

4.7.7 Being honest and maintain confidentiality.

4.8 Specific Duties and Functions of UMMC-MREC Personnel

4.8.1 UMMC-MREC Chair

- a. Recommends UMMC-MREC members in accordance with item 4.2.
- b. Recommends policy amendments and changes.

- c. Presides over meetings.
- d. Represents UMMC-MREC in national and international ethics forum.
- e. Liaises with stakeholders outside UM and UMMC.
- f. Oversees the operations of the UMMC-MREC and all subcommittees.
- g. Supervises the management of the UMMC-MREC Office.
- h. Acts on suggestions, complaints, and queries from stakeholders.
- i. Plans and recommends basic training, orientation, and continuing education of UMMC-MREC members and secretariat staff to the UMMC and UM administration.
- j. Ensures UMMC-MREC compliance with international, national, and institutional policies governing human subject research.
- l. Ensures budget adequacy for UMMC-MREC operations and activities.

4.8.2 Deputy Chair

- a. Chairs meetings when the Chair is absent or unable to perform the duties of the Chair.
- b. Assume the responsibilities of the Chair in his absence.
- c. Assist the Chair in all policy and operational decisions, and execution of the Chair's duties.

4.8.3 Secretary

- a. Manages the secretariat.
- b. Prepares and issues the schedule of every UMMC-MREC meeting.
- c. Notifies Chair, committee members and Secretariat of meetings
- d. and events.
- e. Prepares the meeting agenda and ensure all necessary documents are attached to the agenda (by secretariat staff).
Distributes the agenda and papers for UMMC-MREC meeting.
- f. Ensure completeness of the new applications prior to review by Chair/Deputy Chair.
- g. Ensure completeness of submissions for amendments/notifications/other types of reporting (secretariat staff).
- h. Distributes the agenda and papers for UMMC-MREC meeting.
- i. Provide secretariat support to the sub-committees (secretariat staff).
- j. Sends out invitations to Principal Investigator(s) notifying the date to attend the UMMC-MREC meeting at least three (3) working days in advance.
- k. Prepares the venue of the meetings (secretariat staff).
- l. Takes minutes of the meeting.
- m. Is not eligible for voting in the UMMC-MREC meeting.
- n. Ensures the minutes of the meeting which is tabled is checked by the chairperson prior the next meeting.
- o. Notifies applicants on decisions taken at the meeting and taking other follow-up action as necessary.
- p. Archives the meeting records (secretariat staff).
- q. Entertains enquiries regarding the operation of UMMC-MREC and application process (both)
- r. Assist applicants on the application process (both).

- s. Refer to the UMMC-MREC Chair any suggestions, complaints, or grievances of research participants, PIs, and/or sponsors (both).
- t. Do other UMMC-MREC related duties that maybe requested of him/her by the UMMC-MREC Chair when necessary (both).

Assistant Secretary

- a. Assume the duties of the Secretary in the absence of the Secretary
- b. Assist the Secretary in the performance of the Secretary's duties

4.8.4 UMMC-MREC Members

- a. Make a timely and thorough review and decision regarding protocols given to them for evaluation (**See SOP II: INITIAL REVIEW PROCEDURE** for timelines).
- b. Familiarize themselves with the SOPs of the UMMC-MREC, terms of reference, and international and national guidelines on research ethics.
- c. Participate actively in meetings of UMMC-MREC. In the event of three consecutive absences without valid reason, the member may be recommended to be replaced.
- d. Participate in decision-making for appropriate action on recommendations based on monitoring reports from subcommittees.
- e. Participate in the review of the progress reports, final reports, and other amendments presented during the UMMC-MREC meeting.
- f. Maintain confidentiality of the documents and deliberations of UMMC-MREC meetings.
- g. Declare any conflict of interest in general and for specific protocols for review.
- h. Participate in required training with proof of attendances (examples: the use of new SOPs)
- i. Submit an updated and signed CV at the start of each term of appointment.
- j. Refer to the UMMC-MREC Chair any suggestions, complaints, or grievances of research participants, PIs, and/or sponsors.
- k. Do other UMMC-MREC related duties that maybe requested of him/her by the UMMC-MREC Chair when necessary.

4.8.5 Subcommittee Chair

- a. Presides over subcommittee meetings.
- b. Liaises directly with other UMMC-MREC members and secretariat staff.
- c. Invites independent consultants to provide special expertise for specific situations.
- d. Performs other UMMC-MREC related tasks that may be assigned to him/her by the UMMC-MREC Chair.

4.8.6 Subcommittee Members

- a. Familiarize themselves with the UMMC-MREC SOPs and terms of reference.
- b. Participate actively in the Subcommittee meetings and activities.
- c. Recommend appropriate action on the issues at hand.

- d. Maintain confidentiality of the documents and deliberations of Subcommittee Meetings.
- e. Declare any conflict of interest in general and for specific protocols review.
- f. Submit an updated and signed CV at the start of each term of appointment.
- g. Do other Subcommittee-related duties that maybe requested by the Subcommittee Chair.

4.8.7 UMMC-MREC Secretariat Staff

- a. Manage protocol submissions, review, decisions and post-review (both)
- b. Organize an effective and efficient tracking procedure for each protocol received.
- c. Maintain the UMMC-MREC files including protocols, reports references and other document files, and ensuring their security and confidentiality.
- d. Organize UMMC-MREC meetings (**see SOP II- 8.0: MREC MEETING WORKFLOW**)
- e. Prepare meeting agenda and minutes (Secretary)
- f. Facilitate, document and archive training for UMMC-MREC members and secretariat staff.
- g. Organize the preparation, review, revision and distribution of SOPs and guidelines (Secretary).
- h. Provide the necessary secretariat support for UMMC-MREC-related activities.
- i. Perform other related functions that may be assigned by the UMMC-MREC Chair.

5.0 INDEPENDENT CONSULTANTS

- 5.1 The UMMC-MREC Chair determines and invites the independent consultants based on protocols submitted for review, as and when the need arises.
- 5.2 The invitation includes the responsibilities and functions of the Independent Consultant as follows:
 - a. Fill and sign the following forms when requested:
CONFIDENTIALITY AGREEMENT and **CONFLICT OF INTEREST DISCLOSURE**
 - b. Provide review and opinion on the assigned protocol. This may be through the use of the **STUDY PROTOCOL ASSESSMENT FORM** and **INFORMED CONSENT ASSESSMENT FORM**
 - c. Submit review report and when necessary possible to attend the UMMC-MREC meeting for the deliberations on the said protocols.
 - d. Return all protocol-related materials to the UMMC-MREC Secretariat Staff after review.
 - e. Submit an updated and signed CV upon appointment.

6.0 HONORARIUM FOR MEMBERS AND CONSULTANTS

- 6.1 The UMMC-MREC Chair initiates the recommendation of honorarium or increase thereof, with the Chair, BOM-UMMC.
- 6.2 Only UMMC-MREC lay members and independent consultants outside of FOM-UM/UMMC are compensated for attending meetings and other UMMC-MREC related-activities.
- 6.3 All UMMC-MREC members receive appreciation in terms of sponsorship to attend educational events related to ethics in research.
- 6.4 The recommendation will be submitted to the UMMC management through the submission of the UMMC-MREC budget.
- 6.5 Approval of honorarium:
 - a. The Chairman, BOM-UMMC may approve or disapprove the recommendation.
 - b. Approval or disapproval will be indicated in the approval of the UMMC-MREC budget or amendment thereof.
- 6.6 Communication of honorarium information:
 - a. UMMC-MREC members are informed of the honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations of UM and UMMC.
 - b. UMMC-MREC members and independent consultants shall acknowledge the information upon receipt of notification.

7.0 REFERENCE DOCUMENTS

| <u>Document</u> | <u>Document Number</u> |
|--|------------------------|
| a. Malaysian Guidelines for Good Clinical Practice, 2 nd Edition 2004: Section 3, Institutional Review Board / Independent Ethics Committee | Not applicable |
| b. FDA, CFR Part 56 – Institutional Review Board | Not applicable |
| c. International Committee on Harmonization of Good Clinical Practice (ICH-GCP) guidelines | Not applicable |
| d. Terms of Reference of Medical Ethics Committee, UMMC, 6 October 2015 | Not applicable |