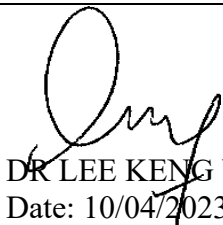





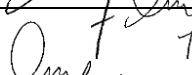
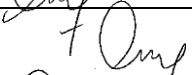
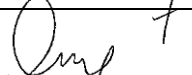


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REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Initials of MREC Secretary
0	All	01/03/2011	Version 1.0, first issue	
1	All	07/01/2014	Version 2.0, new format with additional information	
2	8.2	12/06/2015	Revised definition of lay members	
3	8.3.8, 8.10	04/07/2016	Update in quorum requirement and appointment of MREC member	
4	8.3.8, 8.10	22/12/2018	Update in quorum requirement and appointment of MREC member	
5	8.9.3	09/11/2022	Clarification on wording for responsibilities of MREC member	
6	6.1,6.2, 7.1, 7.2, 8.3, 8.3.7, 8.4.2	10/04/2023	6.1,6.2, 7.1, 7.2, 8.3 – updated NIH secretary to NIH Manager as per new NIH structure. 8.3.7 – Clarify on reappointment for inactive members 8.4.2 – Clarification on vote counting for MREC Secretary and MREC Secretariat.	


7	8.6	06/03/2026	Version 5.0 – clarification of internal verification for resignation of members	
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1. PURPOSE

The Medical Research and Ethics Committee (MREC) of the Ministry of Health (MOH) is established on 2002 to provide independent guidance, advice and decision on ethical issues of health research involving human subjects conducted by staff of the MOH or conducted by non-MOH researchers using facilities of the MOH. The MREC may act as an 'Independent Ethics Committee' for non-MOH institutions. The MREC will safeguard the rights, safety and well-being of all trial subjects. Special attention shall be given to trials that include vulnerable subjects.

The MREC is independent in its reflection, advice and decision. The MREC is constituted according to the 'Malaysian Guidelines for Good Clinical Practice' and operates under the authority of the Director-General (DG) of Health Malaysia. The MREC complies with ethical principles as outlined in the Declaration of Helsinki, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), the Belmont Report, Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO), and ICH Guideline of Good Clinical Practice.

2. SCOPE

This SOP provides the framework for constitution, responsibilities and activities of the MREC.

3. ABBREVIATIONS

CIOMS	Council for International Organizations of Medical Sciences
CV	<i>Curriculum vitae</i>
DDG (R&TS)	Deputy Director-General of Health (Research & Technical Support)
DG	Director-General of Health Malaysia
ICH	International Conference on Harmonization
MOH	Ministry of Health Malaysia
MREC	Medical & Research Ethics Committee
NIH	National Institutes of Health
SAE	Serious adverse event
WHO	World Health Organization

4. GLOSSARY

None

5. REQUIRED AND RELATED DOCUMENT

#	Document #	Document title
1.	SOP 0-1	Guidance for Preparation of Standard Operating Procedures
2.	SOP 1-2	Confidentiality / Conflict of Interest Agreement
3.	SOP 1-3	Education of Members and Secretariat
4.	SOP 1-4	Independent Experts
5.	SOP 2-1	Research Submission
6.	SOP 4-1	Preparation for Agenda, Meeting Procedures and Minutes
7.	SOP 5-1	Maintenance, Archival and Disposal of Study and Non-Study Files
8.	TP 1-1-1	Curriculum vitae
9.	TP 1-1-2	Appointment Letter of Chairperson
10.	TP 1-1-3	Appointment Letter of Deputy Chairperson
11.	TP 1-1-4	Appointment Letter of Member
12.	TP 1-1-5	Appointment Letter of Secretary

6. PROCEDURES

6.1. Appointment of new and replacement members

Step #	Process	Responsibility
1.	Propose nominees.	All members
2.	Examines list of nominees and finalize recommendation.	Chairperson
3.	Contacts nominees to obtain their CVs.	Secretary
4.	Submit CVs.	Nominees
5.	Receives CVs and prepares memo.	Secretary
6.	Examines memo If ok, signs and go to step 7 OR if not ok, go to step 5 .	Chairperson
7.	Examines list of nominees. If agree, go to step 8 OR if disagree, go to step 2 .	DDG (R&TS)
8.	Examines list of nominees. If agree, to step 9 OR if disagree, go to step 7 .	DG
9.	Informs Secretary to prepare appointment letters.	Chairperson
10.	Prepares appointment letters.	Secretary
11.	Examines appointment letters. If ok, go to step 12 OR if not ok, go to step 10 .	Chairperson
12.	Examines appointment letters. If ok, go to step 13 OR if not ok, go to step 11 .	DDG (R&TS)
13.	Examines appointment letters.	DG

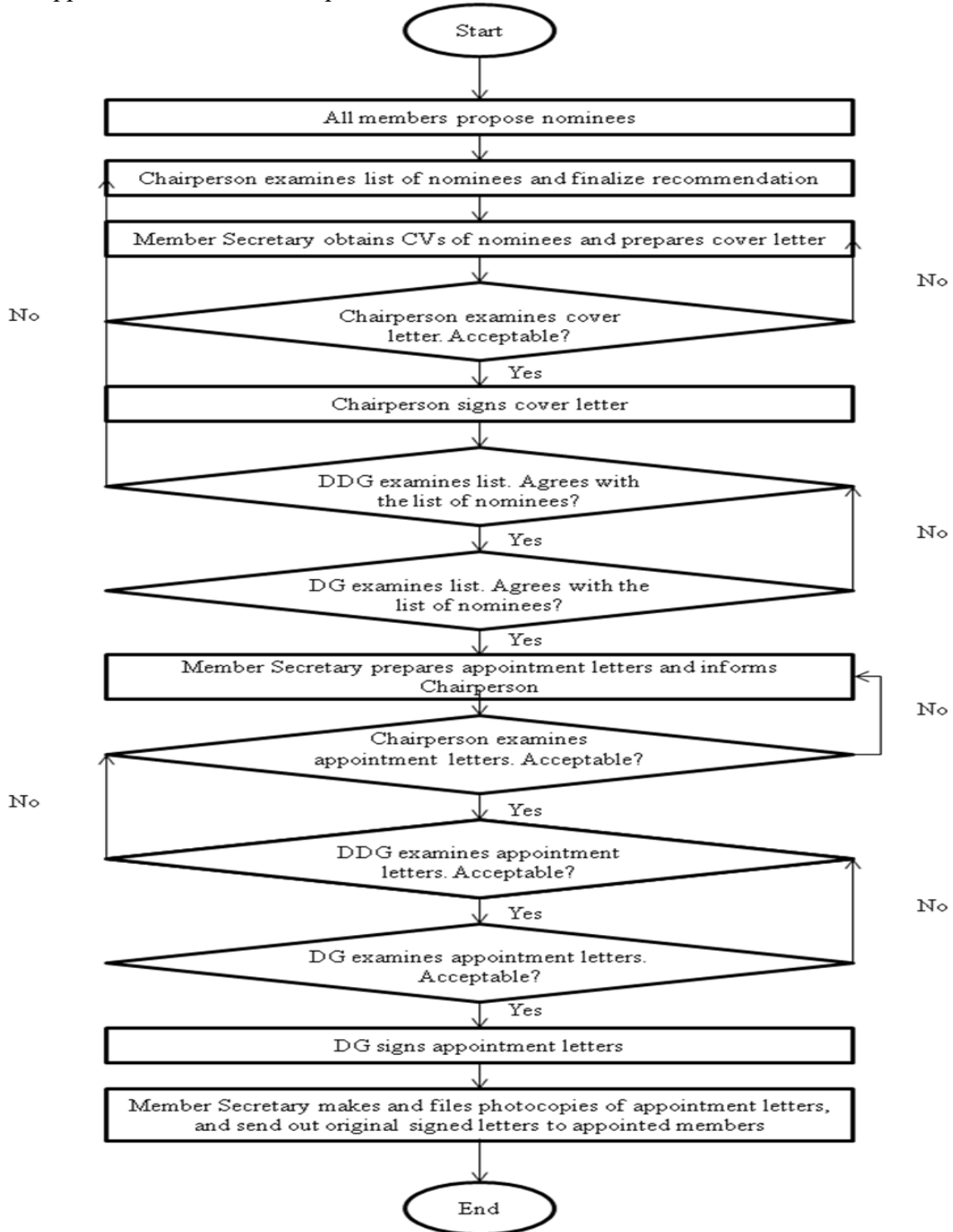
	If ok, sign and go to step 14 OR if not ok, go to step 12.	
14.	Receives signed appointment letters.	Chairperson
15.	Makes and files photocopies of appointment letters. Send out original signed letters to appointed members.	Secretary

6.2. Appointment of new and replacement Secretary

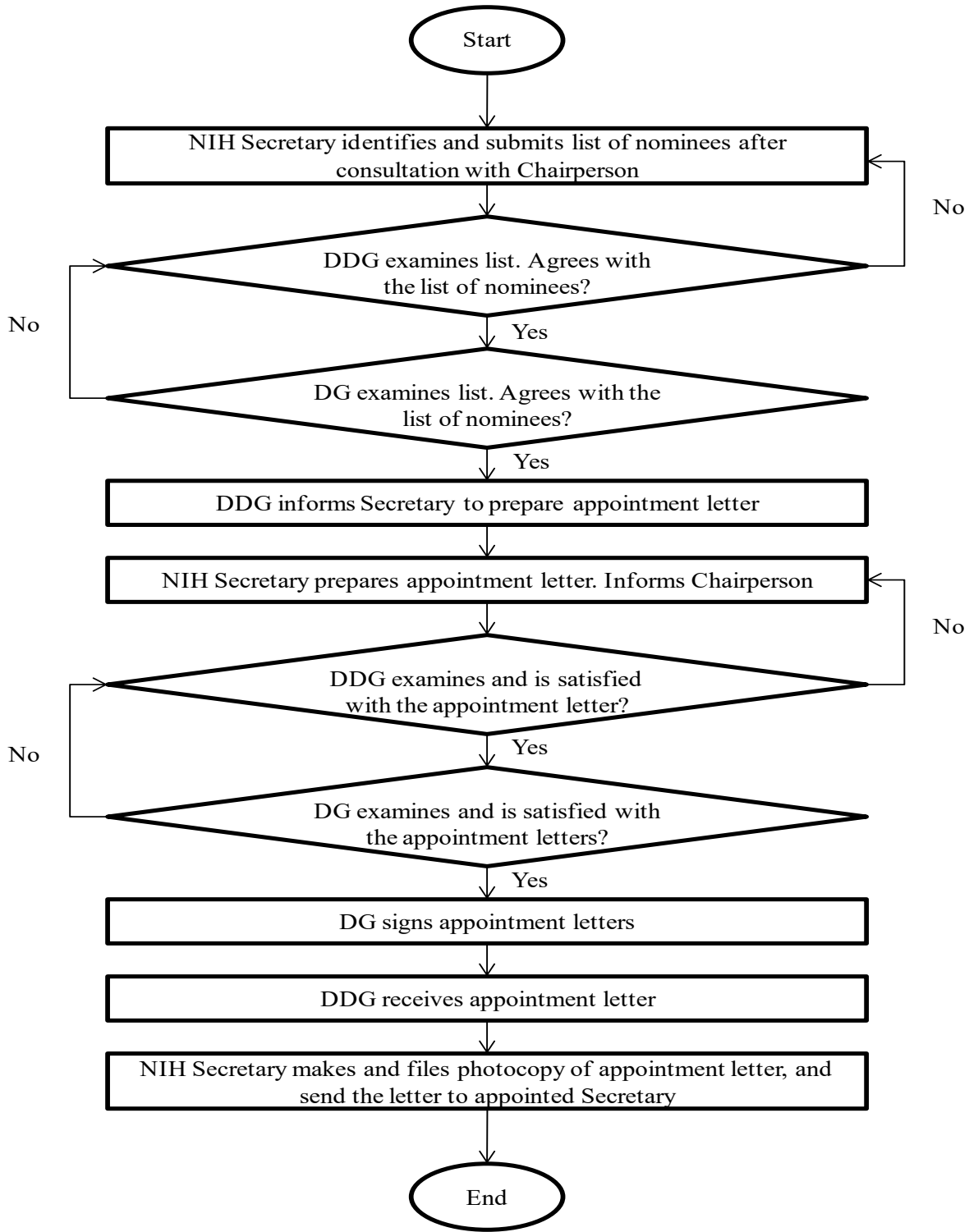
Step #	Process	Responsibility
1.	Identifies and submit list of nominees after consultation with Chairperson.	NIH Manager
2.	Examines list of nominees. If agree, to step 3 OR if disagree, go to step 1.	DDG (R&TS)
3.	Examines list of nominees. If agree, inform DDG (R&TS) OR if disagree, go to step 2.	DG
4.	Informs Secretary to prepare appointment letter	DDG (R&TS)
5.	Prepares appointment letter	Secretary
6.	Examines appointment letter. If ok, go to step 7 OR if not ok, go to step 5.	DDG (R&TS)
7.	Examines appointment letters. If ok, signs letters OR if not ok, go to step 6.	DG
8.	Receives appointment letter and sends to NIH Secretary.	DDG (R&TS)
9.	Makes and files photocopy of appointment letter. Send letter to appointed Secretary.	Secretary

7. FLOWCHART

7.1. Appointment of new and replacement members



7.2. Appointment of new and replacement Secretary (NIH Manager – Refer to PDF file”**



8. DETAILED INSTRUCTIONS

8.1. Ethical Basis

- 8.1.1. The MREC is guided in its reflection, advice and decision by the ethical principles expressed in the *Declaration of Helsinki*
- 8.1.2. The MREC makes further reference to the *International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)*, and the *Belmont Report*.
- 8.1.3. The MREC establishes its own standard operating procedures based on the *Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO)*, and *ICH Guideline of Good Clinical Practice* as well as *Malaysian Guidelines for Good Clinical Practice*.
- 8.1.4. The MREC seeks to fulfil the requirements for international assurances and is established and functions in accordance with Malaysian law and regulations.
- 8.1.5. The MREC seeks to be appropriately informed, by researchers and target populations of the impact of the research it has approved.

8.2. Composition of the MREC

- 8.2.1. The MREC is composed of **at least 5 voting members**.
- 8.2.2. Members are grouped into 2 Panels or more. Each Panel will have not less than 10 voting members. The placement of members in each Panel is decided by the Chairperson. Members can request approval of the Chairperson to change to the other Panel.
- 8.2.3. Unless otherwise determined by the MREC, one Panel will meet on the second Tuesday of every month whereas another Panel will meet on the fourth Tuesday of the month.
- 8.2.4. Each Panel shall include at least one member whose has a medical qualification, at least one member whose has a Science qualification and research experience, at least one non-medical/non-scientific member; and at least one member independent of the MOH.
- 8.2.5. The members shall have various backgrounds to promote complete and adequate review of research commonly conducted by the MOH.
- 8.2.6. Scientific members (non-medical) may include pharmacists, nurses, scientists, statisticians, allied health personnel, etc.
- 8.2.7. Non-medical/Non-scientific members (Lay members) are those possessing non-health sciences qualifications. They may include lawyers, religious leaders, teachers, administrators, etc.
- 8.2.8. Each Panel shall not consist entirely of one sex or of one ethnic group.
- 8.2.9. Members are appointed based on their personal capacities with expertise in their respective fields, and experience in research and ethics

8.3. Appointment of Members, Secretary and Secretariat

- 8.3.1. All members are appointed by the DG. All nominations of members must be endorsed by the DDG (R&TS) before submitting for the DG's approval, **at least 2 months** before the expiry of the term of office of the sitting MREC.
- 8.3.2. All members can submit nominations for Chairperson, Deputy Chairperson and members, to the sitting Chairperson.
- 8.3.3. The Chairperson will examine the nominations and submit a finalized list to the DDG (R&TS) for endorsement and to the DG for approval.
- 8.3.4. The finalized list of nominees must be accompanied by a copy of their *curriculum vitae* (see **TP 1-1-1**).
- 8.3.5. The DG makes the final decision on the appointment of the Chairperson, Deputy Chairperson and members based on their experience, qualifications and credibility in research and are not restricted by the names submitted by the Chairperson.
- 8.3.6. The Secretary is nominated by the NIH Manager after consultation with the Chairperson. The nomination must be endorsed by the DDG (R&TS) and submitted to the DG for approval. The sitting Secretary prepares appointment letters [**TP 1-1-2, TP 1-1-3, TP 1-1-4, TP 1-1-5, TP 1-1-6** (only applicable for secretariats who are medical officers)] and submits via DDG (R&TS) to DG for signature.
- 8.3.7. Members are appointed for a period of 2 years. Appointments may be renewed by the DG with no limit to the number of renewals unless members have been inactive for period of 6 months (have not attended any meetings for the past 6 months or have not reviewed any studies for the past 6 months).
- 8.3.8. In the event that the Deputy Chairperson or any member resigns from the MREC, the Chairperson will submit nomination for a replacement as soon as possible for the consideration of the DDG (R&TS) and the DG. The new Deputy Chairperson or member will serve out the remainder of the 2-year term of the previous Deputy Chairperson or member.
- 8.3.9. In the event that any member resigns/ retires from MOH during the appointment term, the member may continue his/ her tenure until completion of the term without interruptions of having to resign/ re-appointed as a member. The Chairperson will issue a letter to state the continuance of the member's appointment as an independent member from MOH.
- 8.3.10. If the Chairperson resigns, the Deputy Chairperson after consultation with the other members will submit nomination for a replacement as soon as possible for the consideration of the DDG (R&TS) and the DG. The new Chairperson will serve out the remainder of the 2-year term of the previous Chairperson.
- 8.3.11. If the Secretary resigns, the Chairperson will inform the DDG (R&TS) and will submit nomination for a replacement as soon as possible for the consideration of the DG. The new Secretary will serve out the remainder of the 2-year term of the previous Secretary.

8.4. Allocation of Secretariat Staff

- 8.4.1.** Staff may be permanent or temporary government employees.
- 8.4.2.** Permanent government employees comprising of various categories are allocated by the NIH Manager from the Sector of Ethics & Research Surveillance, NIH Manager Office. The duration of service of these employees in the MREC Secretariat is determined by the NIH Secretary.
- 8.4.3.** The permanent government employees comprising of medical officers may be appointed as Secretariat
- 8.4.4.** Temporary employees are identified, interviewed and appointed by the NIH Manager/ Secretary. The duration of employment is determined by the NIH Manager / Secretary and must adhere to Federal Treasury regulations.

8.5. Membership Requirements

- 8.5.1.** Potential members are required to submit their signed CV (see **TP 1-1-1**) to the Secretary. A copy of the CV of appointed members will be kept in an MREC membership file. Each member must submit a signed updated CV to the Secretary before the end of January of the following year.
- 8.5.2.** Members are appointed based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the MREC's work.
- 8.5.3.** MREC members work on behalf of the MOH and are indemnified by the MOH against all litigations that may arise from the work of the MREC.
- 8.5.4.** Members must disclose all manners of conflict of interest in a project or proposal being reviewed, monitored and audited by the MREC.
- 8.5.5.** The MREC decides the extent to which members who have a conflict of interest may participate in the review and decision on a research application (see **SOP 1-2 Confidentiality / Conflict of Interest Agreement**).
- 8.5.6.** Members must sign a Confidentiality / Conflict of Interest Agreement before the start of their term. The Confidentiality / Conflict of Interest Agreement is to protect the confidentiality of all information disclosed to the member in the course of his/her duties in the MREC.
- 8.5.7.** The MREC will include new members every few years but will also strive to ensure continuity within the MREC.

8.6. Resignation, Termination and Replacement of Members

- 8.6.1.** Members may resign their appointments by submitting a letter of resignation to the DG with a copy to the Chairperson.
- 8.6.2.** The Secretariat shall verify the receipt of the formal resignation letter has been submitted in accordance to 8.6.1. Then, a copy shall be retained in the respective member file for documentation purposes.
- 8.6.3.** Members may be recommended by the MREC with endorsement of the DDG(R&TS), to the DG for termination from MREC, should the Chairperson or

another member provide written justifications to the (other) members and there is unanimous agreement.

- 8.6.4.** MREC Secretary may resign from his/her position, according to **Section 8.6.1**. New Secretary will be appointed following the **Section 8.3**.
- 8.6.5.** The Secretary will inform the Chairperson of any members who fail to attend 3 consecutive MREC Panel meeting or fail to conduct 3 consecutive full-board assigned primary reviews, without prior notification to the Secretary/ Secretariat. The Secretary shall request such members to provide written justifications for their failure to perform their duties. The Chairperson will review those justifications and decide whether to table to the MREC for agreement to recommend the termination of those members to the DG.
- 8.6.6.** Replacements for members who have resigned or have been terminated, shall be appointed by the DG as soon as possible to satisfy the requirement of the minimum number of members as stated in **Section 8.2**. The procedure for nominating replacements to the DG follows that stated in **Section 8.3**.

8.7. Independent Experts

- 8.7.1.** The MREC may be further supported by Independent Experts in its reflections on specific protocols where there is no subject matter expert in the MREC or when there is a need for advice on specific ethical issues.
- 8.7.2.** Independent Experts are appointed by the Chairperson of the MREC as and when there is a need. The procedure, terms of reference and duration of appointment of such experts are stated in **SOP 1-4**.
- 8.7.3.** The Secretary will compile a list of potential independent experts for the consideration of the Chairperson.
- 8.7.4.** There will be one Independent Expert from the National Pharmaceutical Control Bureau to provide advice on pharmaceuticals. This person may be invited to attend MREC meetings.

8.8. Conditions of Appointment

- 8.8.1.** Members and Independent Experts are appointed to the MREC under the following conditions:
 - 8.8.1.1.** Willing for his/her full name, profession and affiliation to be publicly disclosed;
 - 8.8.1.2.** All financial accountability, reimbursement for work and expenses, if any, within or related to the MREC to be recorded and made available to the public upon request.
 - 8.8.1.3.** All MREC members and Independent Experts must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, research information, and related matters.

8.9. Responsibilities

8.9.1. MREC Chairperson

- 8.9.1.1.** Ensures the MREC carry out its responsibilities in accordance with established SOPs.
- 8.9.1.2.** Reviews and makes decision on studies undergoing exempt review.
- 8.9.1.3.** Examines report of reviewer(s) and make decision on studies undergoing expedited review. The Chairperson may delegate this authority to other MREC members/ Secretary/ Secretariat.
- 8.9.1.4.** Signs all MREC approval/ disapproval letters and other related letters unless conflict of interest is present.
- 8.9.1.5.** Maintains communication with investigators, Secretary, Secretariat, MREC members and other stakeholders.
- 8.9.1.6.** Provides oversight and leadership in continuing review of approved studies, site audits, and monitoring of SAEs.
- 8.9.1.7.** Chairs full board meetings.
- 8.9.1.8.** Monitors the continuing training of members and secretariat staff.
- 8.9.1.9.** Nominates individuals to be appointed as Deputy Chairperson, MREC members, Secretary & Secretariat.
- 8.9.1.10.** Appoints Independent experts & Adverse Event Subcommittee (AESC) member.
- 8.9.1.11.** Provide technical support/ consultation on MREC related matters as and when required.
- 8.9.1.12.** Signs approval of new and revised SOPs.

8.9.2. Deputy Chairperson

- 8.9.2.1.** Carries out the responsibilities of the Chairperson in his/ her absence or when the Chairperson has a conflict of interest.
- 8.9.2.2.** In the absence of both the Chairperson and Deputy Chairperson or when both has a conflict of interest, the Chairperson will appoint one MREC member to serve as the Chairperson during the unavailability of the Chairperson and the Deputy Chairperson.

8.9.3. MREC Members

- 8.9.3.1.** Attend and participate actively in MREC meetings.
- 8.9.3.2.** Review, discuss and decide on approval of research submissions, including any restrictions and/or conditional approval
- 8.9.3.3.** Terminations and suspensions of approval of research submissions.
- 8.9.3.4.** Review, discuss and decide on approval of amendments of research documents.
- 8.9.3.5.** Maintain confidentiality of documents of MREC and deliberations at MREC meetings.

- 8.9.3.6.** Review serious adverse event reports and recommend appropriate action(s).
- 8.9.3.7.** Review protocol deviations/ violation and recommend appropriate action(s).
- 8.9.3.8.** Review progress reports of approved studies and decide on appropriate actions if necessary.
- 8.9.3.9.** Evaluate final study reports and findings and decide on appropriate action if required.
- 8.9.3.10.** Participate in site audits (oversee conduct) when appointed by the Chairperson.
- 8.9.3.11.** Declare any conflict of interest when required.
- 8.9.3.12.** Participate in continuing education activities in ethics of research involving human subjects.
- 8.9.3.13.** Prepare draft of new and revised SOP if assigned by the Chairperson.
- 8.9.3.14.** Review existing SOPs to identify need for revision if assigned by the Chairperson.
- 8.9.3.15.** Participate in decision on approval of new and revised SOPs.
- 8.9.3.16.** Recommend potential new MREC members and independent experts to the Chairperson to be considered for appointment to the MREC.

8.9.4. Secretary

- 8.9.4.1** Manages operating funds received from the NIH Secretary
- 8.9.4.2** Oversees the daily operations of the MREC Secretariat and adherence to timelines
- 8.9.4.3** Ensure there is sufficient material and facility support for the efficient operation of the MREC secretariat
- 8.9.4.4** Oversees the examinations of new studies and revisions, and make first determination of whether to undergo exempt, expedited or full board review
- 8.9.4.5** Identifies primary reviewers or independent experts, and assigns new studies and amendments for reviews; if necessary
- 8.9.4.6** Oversees the preparation for MREC meetings which include agenda, reports and minutes of Panel meetings
- 8.9.4.7** Prepare minutes of review of studies at full board meetings
- 8.9.4.8** Oversees the preparation of business meetings of MREC and minutes of the meeting
- 8.9.4.9** Oversees the preparation of other MREC related meetings
- 8.9.4.10** Oversees preparation of decision letters and other official correspondence.
- 8.9.4.11** Attend and participate in MREC meetings
- 8.9.4.12** Qualify as part of the quorum for MREC meeting
- 8.9.4.13** Present primary review and consolidated NMRR review reports during Panel meetings
- 8.9.4.14** Presents meeting agenda, past meeting minutes and new projects listed at the Panel meetings

- 8.9.4.15** Oversees the distribution, storage and archiving of MREC documents and correspondences
- 8.9.4.16** Oversees the receipt and distribution of SAE reports to the Serious Adverse Event Sub Committee (SAESC)
- 8.9.4.17** Signs MREC comment letters
- 8.9.4.18** Receive and maintains active communication including responding to queries with investigators, Secretariat, MREC members and other stakeholders
- 8.9.4.19** Oversees preparation for and conduct of site audits
- 8.9.4.20** Oversees the monitoring of approved studies
- 8.9.4.21** Oversees the proper maintenance of members' files including updating of CV and training records
- 8.9.4.22** Participate in continuing education activities in ethics of research involving human subjects and other appropriate training
- 8.9.4.23** Oversees the continual training of MREC members and Secretariat staff
- 8.9.4.24** Monitors and informs the Chairperson when it is time for continuing review of SOPs, when there is a need to develop new SOPs, and existing SOPs need to be revised.
- 8.9.4.25** Review existing SOPs to identify need for revision if assigned by the Chairperson
- 8.9.4.26** Makes corrections to existing SOPs that do not need a revision
- 8.9.4.27** Prepare draft of new and revised SOP if assigned by the Chairperson
- 8.9.4.28** Oversee the maintenance and updating of MREC website
- 8.9.4.29** Oversees the preparation of MREC Annual Report
- 8.9.4.30** Participate in site audits when appointed by the Chairperson
- 8.9.4.31** Heads the secretariat and in charge of all administrative duties of the unit
- 8.9.4.32** Responsible to oversee the secretariat staff's leave, discipline, performance appraisal and related administrative matters
- 8.9.4.33** Provide technical support/ consultation on MREC related matters as and when required
- 8.9.4.34** Conducts any other tasks directed by the Chairperson which include:
 - 8.9.4.34.1** Review revisions of expedited reviewed submissions as and when required
 - 8.9.4.34.2** Review amendments of research documents as and when required
 - 8.9.4.34.3** Review serious adverse event reports and recommend appropriate action(s) as and when required
 - 8.9.4.34.4** Review progress reports of approved studies and decide on appropriate actions if necessary, as and when required
 - 8.9.4.34.5** Evaluate final study reports and findings and decide on appropriate action if required as and when required
 - 8.9.4.34.6** Any other task given

8.9.5. Secretariat staff

8.9.5.1 Process research applications which include:

8.9.5.1.1 Screening the research application and recommend to the Chairperson or Secretary for exempt, expedite or full board reviews

8.9.5.1.2 Prepare, maintain and distribute study files

8.9.5.1.3 Prepare and distribute study documents for review

8.9.5.1.4 Inform primary reviewers and selected expedited reviewers of studies to be reviewed

8.9.5.1.5 Receive assessment reports of primary reviewers, expedited reviewers, and NMRR reviewers, and present to Secretary

8.9.5.1.6 Prepare decision letters and other correspondences for the signature of Chairperson and Secretary, where applicable

8.9.5.1.7 Update status of study approval in NMRR

8.9.5.2 Facilitate all MREC related meetings and preparation of meeting which include:

8.9.5.2.1 Prepare meeting agenda, reports for meeting and minutes of Panel meeting

8.9.5.2.2 Distribute agenda and minutes of meetings

8.9.5.2.3 Record and assist in preparation minutes of review of studies at full board meetings

8.9.5.2.4 Record and prepare minutes of business meetings of MREC

8.9.5.2.5 Prepare other MREC related meeting

8.9.5.3 Track progress of approval of research application

8.9.5.4 Receive and respond to communications with MREC members, investigators and other stakeholders

8.9.5.5 Communicate decisions and information from MREC to investigators

8.9.5.6 Prepare, update and maintain member and staff files

8.9.5.7 File, store and archive all correspondences, MREC documents and study files

8.9.5.8 Store, distribute and archive MREC SOPs and guidelines

8.9.5.9 Maintain and update information in the MREC website

8.9.5.10 Provide and distribute updates on relevant and contemporary issues related to ethics in health research to MREC members

8.9.5.11 Participate in continuing education activities in ethics of research involving human subjects and other appropriate training

8.9.5.12 Coordinate training of MREC members and staff

8.9.5.13 Prepare MREC annual report

8.9.5.14 Participate in site audits when appointed by the Chairperson

8.9.5.15 Assist in review of existing SOPs to identify need for revision if assigned by the Chairperson

8.9.5.16 Assist in making corrections to existing SOPs that do not need a revision

8.9.5.17 Provide technical support/ consultation on MREC related matters as and when required

8.9.5.18 Provide administrative support to the Chairperson and Secretary

8.9.5.19 Conduct any other responsibilities directed by the Chairperson and Secretary which include:

8.9.5.19.1 Review revisions of expedited reviewed submissions

8.9.5.19.2 Review amendments of research documents

8.9.5.19.3 Review serious adverse event reports and recommend appropriate action(s)

8.9.5.19.4 Review progress reports of approved studies and decide on appropriate actions if necessary

8.9.5.19.5 Evaluate final study reports and findings and decide on appropriate action if required

8.9.5.19.6 Any other task given

8.9.5.20 In the absence of the Secretary, the appointed Secretariat will carry out all duties of the Secretary

8.10. Quorum Requirements

8.10.1. The quorum for each convened Panel meeting is at least half of the attending panel or at minimum of 9 members including whichever lesser. The quorum must be satisfied at a meeting in order to issue a valid advice and/or decision. Professional qualifications of the quorum shall consist of at least one medical member, at least one non-medical/non-scientific member (lay member), and at least one member independent of the MOH. This meeting will discuss only study specific matters. MREC Secretary is counted as 1 voting member when he/she attends the meeting. MREC Secretariat members may attend the meeting, and only 1 of the MREC Secretariat member will be counted as 1 voting member.

8.10.2. The quorum for each convened business meeting is at least one third of the total MREC members (including the Chairperson). This meeting will discuss general MREC matters and policies but not study specific matters.

8.11. Dissolution of the MREC

8.11.1. At any point in time, should the MOH cease to exist, the MREC is automatically dissolved.

8.11.2. The MREC may also be dissolved at any time by the DG following written notification to each MREC member.

9. REFERENCES

- 9.1.** Declaration of Helsinki
- 9.2.** The International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
- 9.3.** The Belmont Report
- 9.4.** Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO)
- 9.5.** ICH Guideline of Good Clinical Practice
- 9.6.** Malaysian Guidelines for Good Clinical Practice

10. APPENDIX

None