Authority and Membership

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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	

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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	*Curriculum vitae*
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)

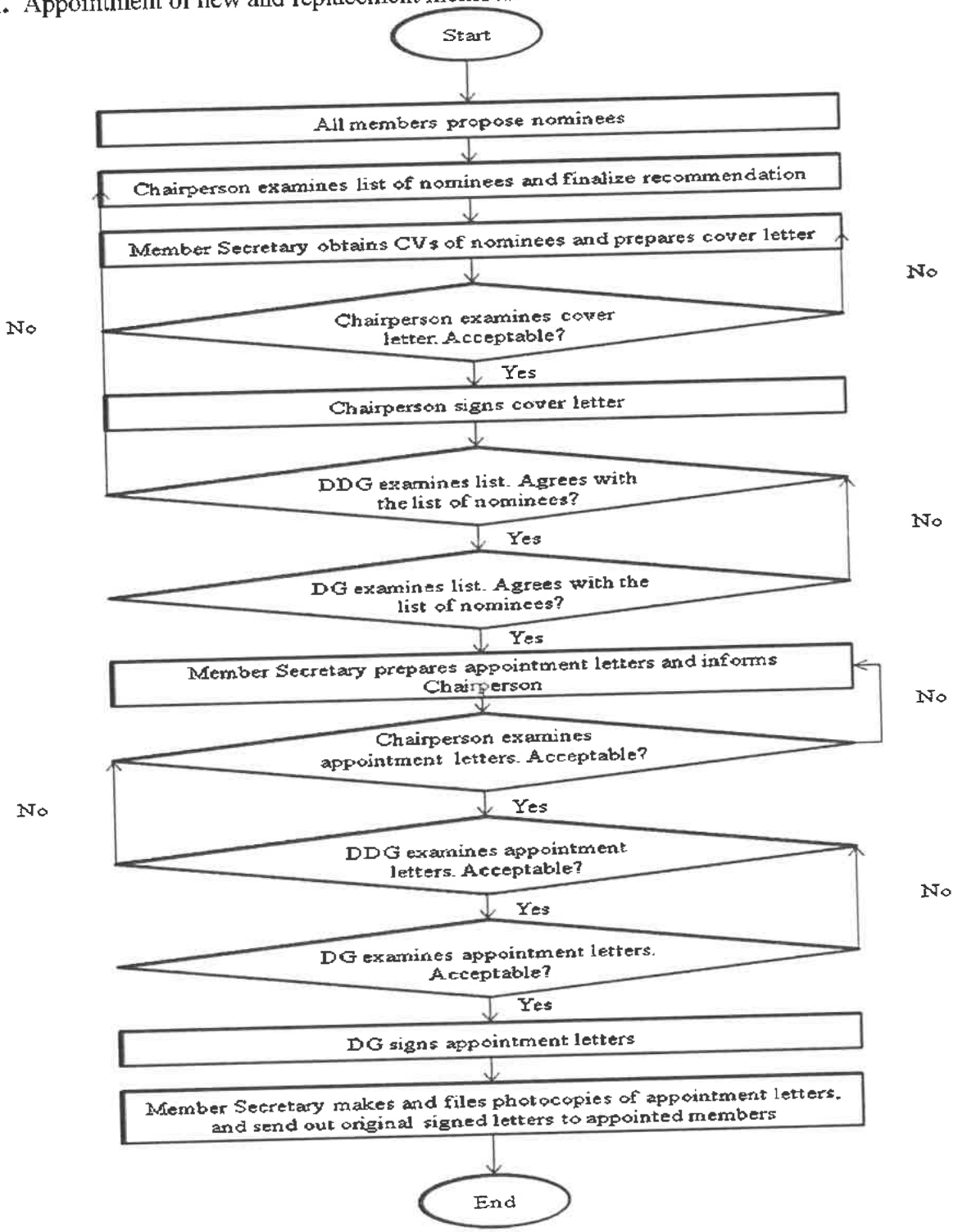
13.	Examines appointment letters. If ok, sign and go to **step 14** OR if not ok, go to **step 12**.	DG
14.	Receives signed appointment letters.	Chairperson
15.	Makes and files photocopies of appointment letters. Send out original signed letters to appointed members.	Secretary

6.2. Appointment of new and replacement Secretary

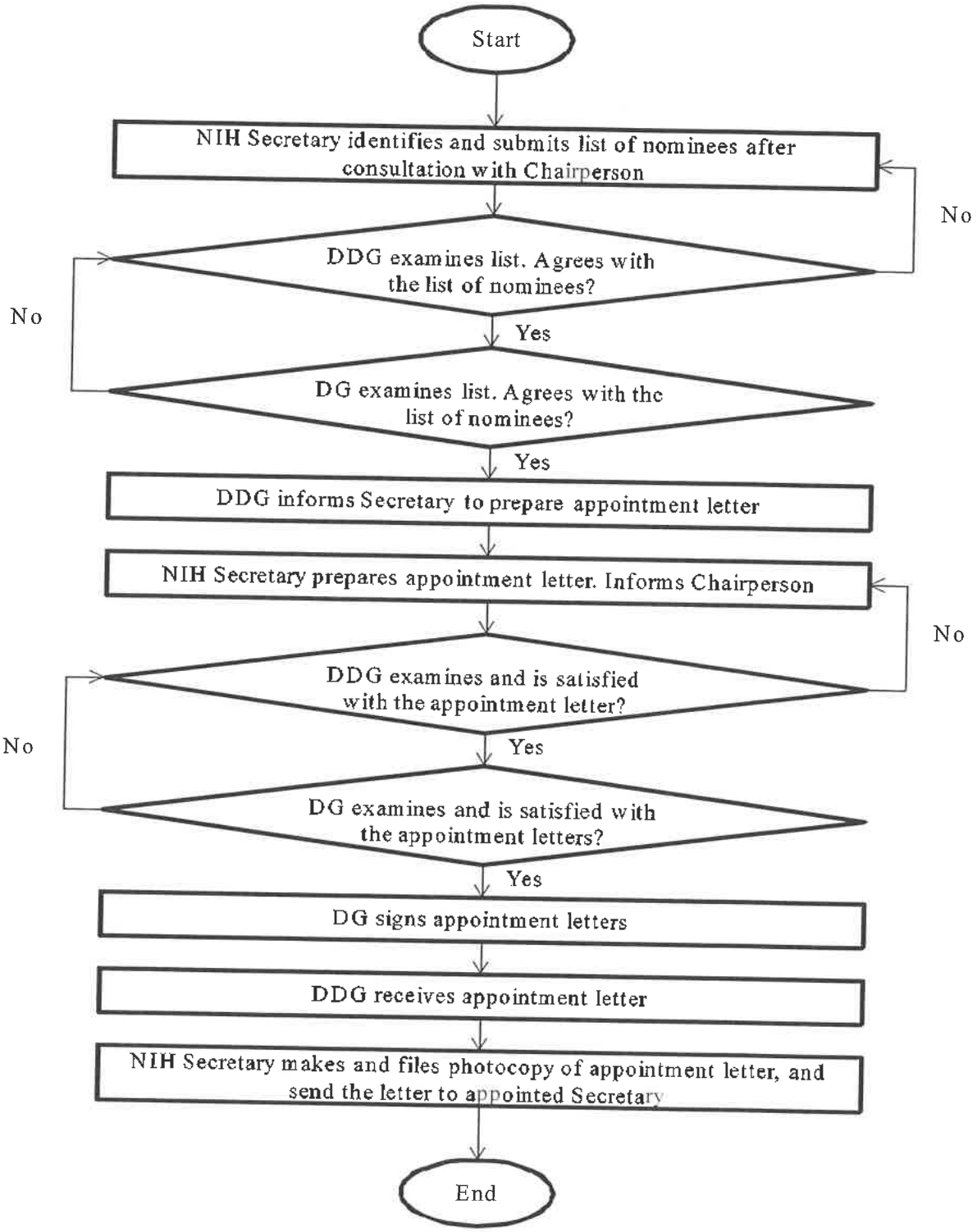
Step #	Process	Responsibility
1.	Identifies and submit list of nominees after consultation with Chairperson.	NIH Secretary
2.	Examines list of nominees. If agree, to **step 3** OR if disagree, go to **step 1**.	DDG (R&TS)
3.	Examines list of nominees. If agree, inform DDG (R&TS) OR if disagree, go to **step 2**.	DG
4.	Informs Secretary to prepare appointment letter	DDG (R&TS)
5.	Prepares appointment letter	NIH 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.	NIH Secretary

7. FLOWCHART

7.1. Appointment of new and replacement members



7.2. Appointment of new and replacement Secretary



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 Secretary 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.

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 Secretary from the NIH Secretariat. 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 / Secretary. The duration of employment is determined by the NIH / 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. 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.

8.6.3. MREC Secretary may resign from his/her position, according to **Section 8.6.1**. New Secretary will be appointed following the **Section 8.3.**

8.6.4. 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.

8.6.5. 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.
8.9.3.3. Review, discuss and decide on approval of amendments of research documents.
8.9.3.4. Maintain confidentiality of documents of MREC and deliberations at MREC meetings.

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

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

Standard Operating Procedure
Confidentiality/ Conflict of Interest Agreement

Document no.:	SOP 1-2
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REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Initials of Member Secretary
0	All	01/03/2011	Version 1.0, first issue	
1	All	14/11/2014	Version 2.0, new format with additional information	
2	8.1.1	04/07/2016	CCOI requirement for appointed members	
3	Item 5 and 8.1.6	19/7/2018	Version 3.0, with new WS 1-2-6 Agreement on Confidentiality for Guest / Observer to MREC Compliance Reviews	

TABLE OF CONTENTS

1. PURPOSE

The purpose of this Standard Operating Procedure is to provide a template for Agreements on Confidentiality / Conflict of Interest (CCOI) (hereon referred to as 'Agreement') and identify who should read, understand, accept, keep in mind, sign and date the Agreement. The procedures provide details when and where to sign as well as to how the signed document should be kept.

2. SCOPE

No individual can participate in an MREC meeting or access MREC documents until that individual has completed and signed an Agreement.

3. ABBREVIATIONS

CCOI	Confidentiality / Conflict of Interest
MREC	Medical Research and Ethics Committee

4. GLOSSARY

Term	Definition
Confidentiality	The non-occurrence of unauthorized disclosure of information
Confidentiality Agreement	Sometimes called Secrecy or Non-Disclosure Agreement. The agreement is designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella or confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that

	the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are 3 key elements in this definition: financial interest, official duties, and professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the MREC and MOH. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.

5. REQUIRED AND RELATED DOCUMENT

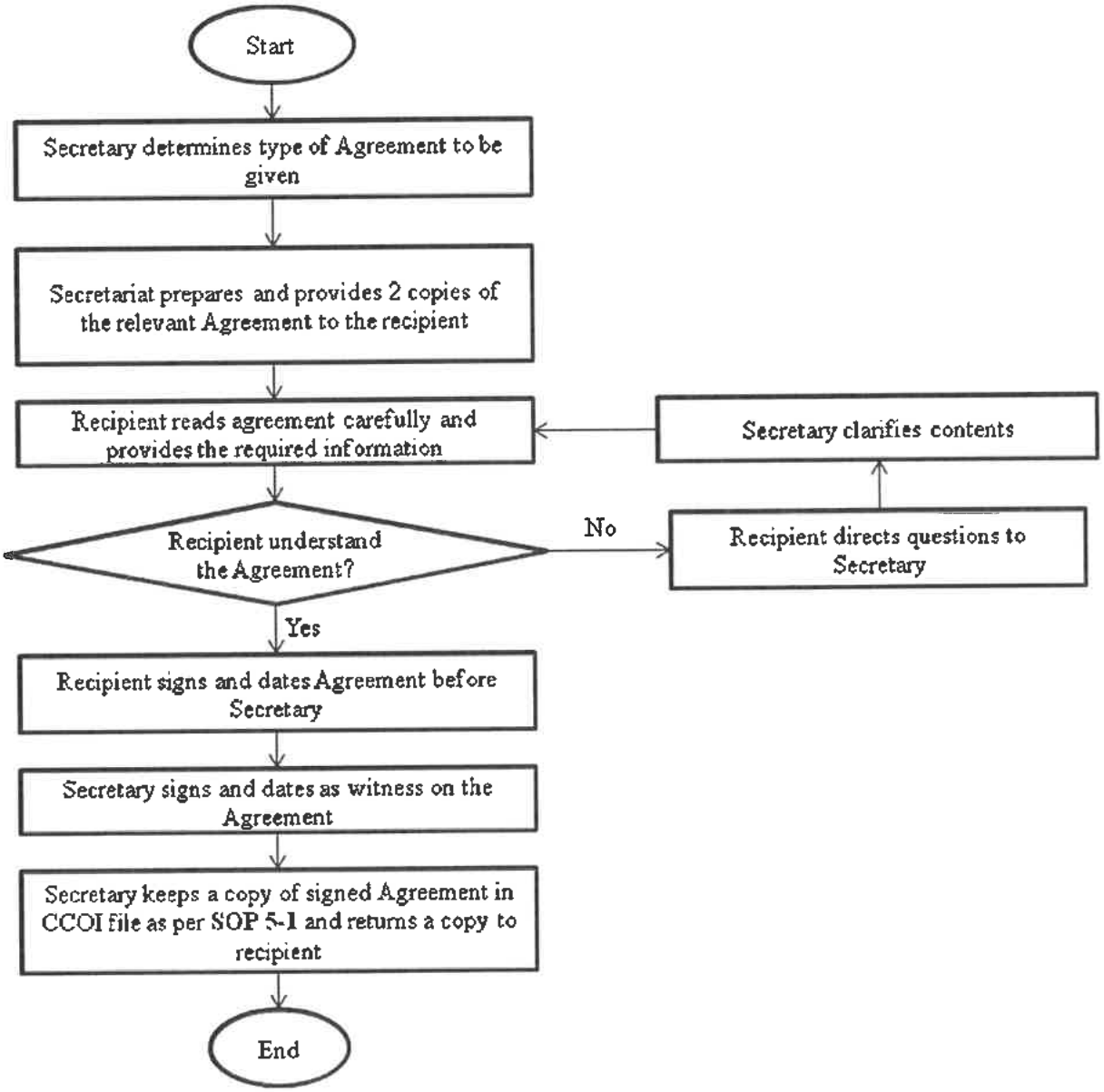
#	Document Title
1.	WS 1-2-1: Agreement on Confidentiality / Conflict of Interest for MREC Members.
2.	WS 1-2-2: Agreement on Confidentiality / Conflict of Interest for members of MREC Secretariat
3.	WS 1-2-3: Agreement on Confidentiality / Conflict of Interest for Independent Experts.
4.	WS 1-2-4: Agreement on Confidentiality for Guest / Observer to MREC meetings
5.	WS 1-2-5: Agreement on Confidentiality For Non-members Requesting Copy(ies) of MREC Document(s)
6.	WS 1-2-6: Agreement on Confidentiality for Guest / Observer to MREC Compliance Reviews

6. PROCEDURE

Step #	Process	Responsibility
1.	Determines the type of Agreement to be given.	Member Secretary
2.	Prepares and provides 2 copies of the required Agreement to relevant personnel.	Secretariat

3.	Reads Agreement carefully and provides required information • If unclear, directs questions to Secretary and Secretary clarifies contents.	Recipient, Member Secretary
4.	Signs and dates Agreement before the Secretary.	Recipient, Member Secretary
5.	Secretary signs and dates as witness on the Agreement.	Member Secretary
6.	Keeps a copy of the signed Agreement in CCOI file as per **SOP 5-1** and returns the other copy to recipient.	Member Secretary

7. FLOWCHART



8. DETAILED INSTRUCTIONS

8.1. Secretary determines the required Agreement to the relevant personnel in the manner as follows:

8.1.1. **WS 1-2-1** for all new MREC members. Secretariat provides the agreement at the beginning of the 2 year term. Members who have been re-appointed and have already signed the **WS 1-2-1** during their previous term do not need to complete a new **WS 1-2-1**

8.1.2. **WS 1-2-2** for all new staff of Secretariat who has access to MREC documents.

8.1.3. **WS 1-2-3** for all new and reappointed Independent Experts.

8.1.4. **WS 1-2-4** for all new Guests / Observers to MREC meetings.

8.1.5. **WS 1-2-5** for all non-members of MREC requesting MREC documents.

8.1.6 **WS 1-2-6** for all new Guests / Observers to MREC Compliance Reviews.

8.2. In the case of non-members of MREC requesting MREC documents, an official request letter is forwarded to the Secretary. If request is approved, an approval letter is prepared

8.3. Secretariat prepares and provides 2 copies of the relevant Agreement to the recepient.

8.4. Repient reads through Agreement and provides the required information.

8.4.1. If unclear of contents of the Agreement, the recepient directs questions to the Secretary.

8.4.2. Member Secretary explains or clarifies the contents of the Agreement.

8.5. The recipient signs and dates copies of the Agreement before the Secretary.
Note: In the case of an Agreement by the Member Secretary, Member Secretary signs and dates Agreement before the MREC Chairperson

8.6. Member Secretary signs and dates as witness.
Note: In the case of an Agreement by the Member Secretary, the witness will be the MREC Chairperson.

8.7. Member Secretary keeps a copy of the signed Agreement in the CCOI file and provides other copy to the recepient for their personal records.

8.8. The CCOI file is kept in a secure cabinet with limited / controlled access as per **SOP 5-1**.

9. REFERENCES

None

10. APPENDIX

None

Standard Operating Procedure
Education of MREC Members, Secretary and Secretariat

Document no.:	SOP 1-3
Date originally issued:	01/03/2011
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DR GURPREET KAUR Date: 04/07/2016	DATO' DR CHANG KIAN MENG Date: 04/07/2016

REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Initials of MREC Secretary
0	All	01/03/2011	Version 1.0, first issue	G.K.
1	All	14/11/2014	Version 2.0, new format with additional information	G.K.
2	8.3.7	04/07/2016	Dateline for training record update	G.K.

TABLE OF CONTENTS

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to inform MREC members, Secretary and secretariat, the need for training and how members should seek to attend training or workshop programmes to update themselves on the progress of research technology, information and ethics.

The Ministry of Health (MOH) recognizes the importance of training and continuing professional development, and will allocate an annual budget for specific training and study visits for MREC members, Secretary and secretariat. New MREC members are required to undergo a training programme prior to joining in any decision making process.

2. SCOPE

The SOP applies to all MREC members, Secretary and secretariat. Detailed procedures are for training funded by the NIH. For others, application and post-training reporting are as per department's requirements but a copy of certificate of participation is to be sent to the Secretariat.

3. ABBREVIATIONS

CIOMS	Council for International Organisations of Medical Sciences
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
MOH	Ministry of Health, Malaysia
MREC	Medical Research and Ethics Committee
NIH	National Institutes of Health

4. GLOSSARY

Term	Definition
Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Orientation	Familiarization of newcomers to the conduct of activities of an organization.
Workshop	A group of people engaged in study or work on a creative project or subject.

5. REQUIRED AND RELATED DOCUMENT

#	Document Title
1.	SOP 1-2: Confidentiality / Conflict of Interest Agreement.
2.	WS 1-3-1: Training Record Form

6. PROCEDURE

6.1. Training for New MREC Members

Step #	Process	Responsibility
1.	Schedules orientation for new members	Secretary
2.	Prepares all relevant review documents and references, and disseminate to new member	Secretary
3.	(a) Conducts introductory training session on relevant review documents and references **(Refer 8.2.3)**	Secretary
	(b) Attends introductory training session	New member(s)
4.	Schedules attendance of new member as an observer at a MREC meeting,	Secretary
5.	Attends MREC meeting as an observer	New member(s)
6.	During the MREC meeting, Chairperson introduces new member to other members	Chairperson
7.	Declares new member has completed orientation and records training in a **WS 1-3-1** to be filed in new member personal file.	Secretary

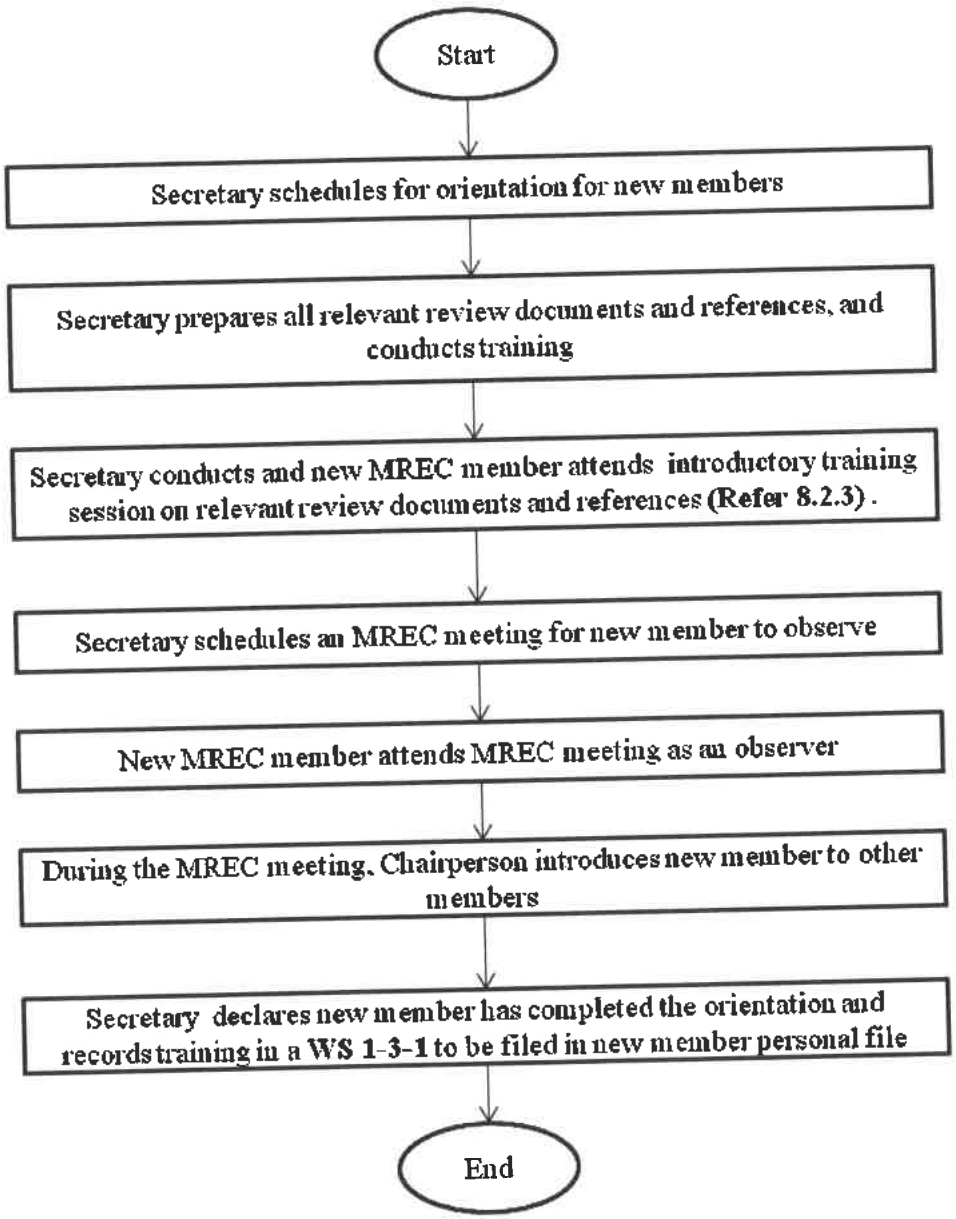
6.2. Continuing Training for MREC Members, Secretary and Secretariat

Step #	Process	Responsibility
1.	Periodically obtain information on relevant training, courses and workshops.	MREC members, Secretary, Secretariat
2.	Selects training that is of interest and submits application to Secretary	MREC members, Secretariat
3.	Compiles information of training and submits application for endorsement	Secretary
4.	Endorses application for MREC members, Secretary and Secretariat. No endorsement required for training application of Chairperson	MREC Chairperson
5.	Submits for approval and funding	Secretary
6.	Reviews and process approval of application	NIH Secretary
7.	a) If approved, attends approved training	MREC members, Secretary, Secretariat
	b) If not approved, informs MREC members, and Secretariat. No further action required.	Secretary

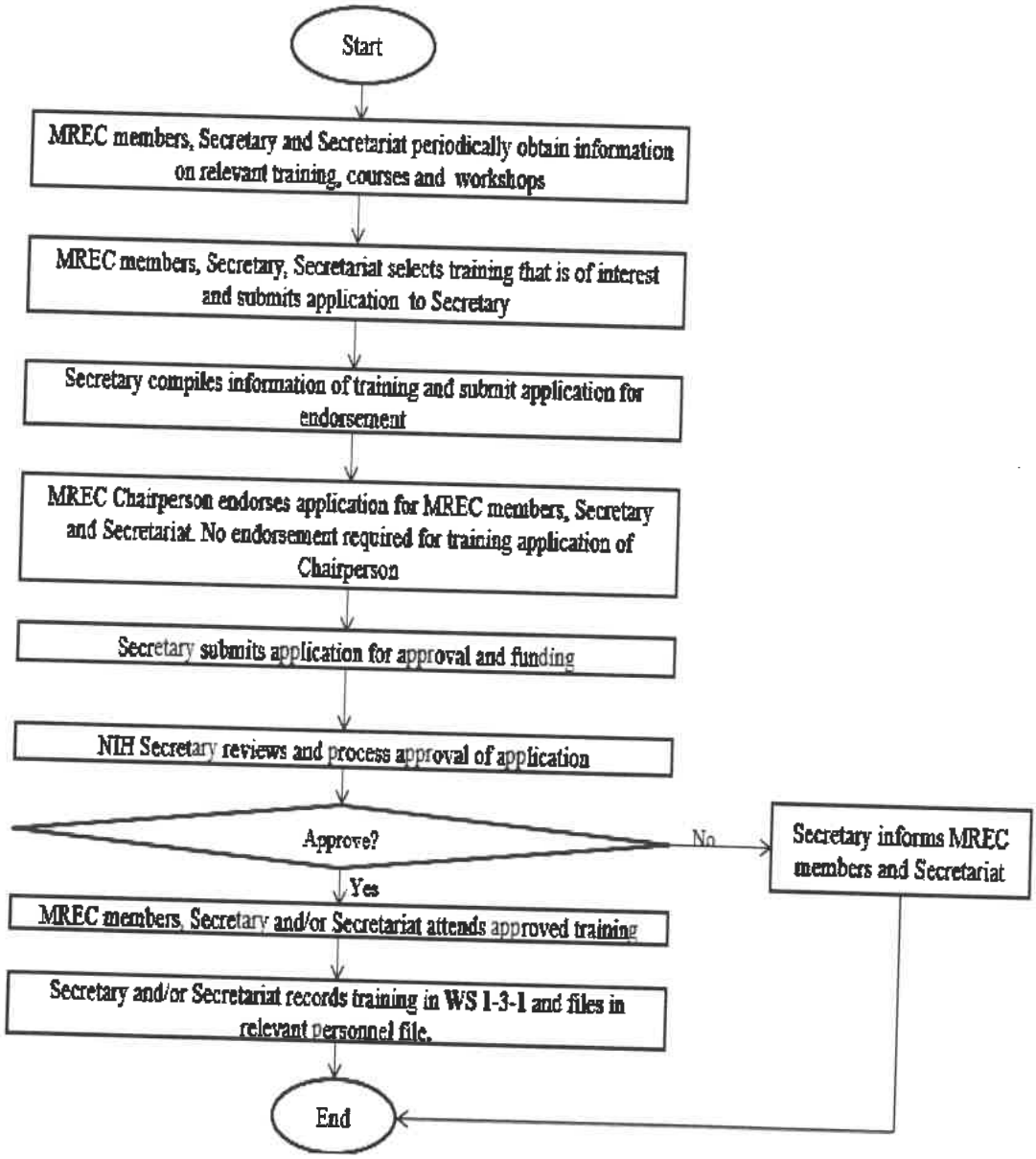
8.	Records training in **WS 1-3-1**	MREC Members, Secretary, Secretariat
9.	Files in relevant personnel file.	Secretary, Secretariat

7. FLOWCHART

7.1. Training for new MREC members



7.2. Continuing training for MREC Members, Secretary and Secretariat



8. DETAILED INSTRUCTIONS

8.1. All MREC members maintains competence by ensuring their knowledge of the following is current:

8.1.1. Good Clinical Practice (GCP).

8.1.2. Declaration of Helsinki.

8.1.3. Ethical issues related to research involving human subjects.

8.1.4. Regulations and guidelines of national and international regulatory agencies such as Malaysia's Drug Control Authority and USA's Food and Drug Administration.

8.1.5. Development in relevant sciences including technical, environmental, health and safety aspects.

8.1.6. Relevant national health, safety, environmental laws and regulations, and related documents.

8.1.7. Audit procedures

8.2. **Training for New MREC Members**

8.2.1. The Secretary schedules orientation for new members once they are officially appointed and have signed an agreement on Confidentiality / Conflict of Interest **(refer SOP 1-2)**.

8.2.2. The Secretary prepares all the relevant review documents and references listed in **8.2.3** and disseminate to new members, upon their appointment to MREC.

8.2.3. The Secretary schedules an introductory training session for new member at a mutually convenient time (this may be prior to the start of the term of appointment) and venue on the following:

8.2.3.1. MREC SOPs and other administrative documents.

8.2.3.2. MREC forms with the Secretary (including use of Primary reviewer forms (WS 2-3-1 and WS 2-3-2) and Follow-up review report (WS 2-3-6)).

8.2.3.3. Declaration of Helsinki.

8.2.3.4. International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS).

8.2.3.5. Belmont Report.

8.2.3.6. World Health Organization, Operational Guidelines for Ethics Committees That Review Biomedical Research, 2000.

8.2.3.7. International Conference on Harmonization, Guideline on Good Clinical Practice (ICH GCP) 1996.

8.2.3.8. Malaysian Guidelines for Good Clinical Practice, Ministry of Health Malaysia, 1999.

8.2.3.9. Glossary of terms used by MREC

8.2.3.10. Training related to areas of risk-benefit assessment, vulnerability, and informed consent form.

8.2.4. Following the introductory training session, the new member attends a MREC meeting as an observer; the new member will not participate in the review and

approval of projects at that meeting. At the meeting, the new member will be introduced to the other members.

8.2.5. Orientation is considered completed once the new member has completed the introductory training session and had attended one MREC meeting as an observer. The completion of orientation will be recorded in the training record of the new member (**WS 1-3-1**).

8.2.6. No member appointed after the effective date of this SOP, may attend a MREC meeting (except as an observer) until his/her orientation is completed.

8.2.7. Orientation is not required for reappointed members without a break in their appointments. Reappointed members with a break of **more than 2 years** in their appointments will need to undergo orientation again.

8.3. **Continuing training for MREC Members, Secretary and Secretariat**

8.3.1. MREC members, Secretary and Secretariat should regularly obtain information about relevant training courses, workshops, conferences, etc. that are periodically announced on websites, bulletin boards and various mass media.

8.3.2. All MREC members are required to attend GCP workshop/ training if it's not attended at the time of appointment.

8.3.3. All Secretariat staff must attend 3 trainings/ year and the training for Secretariat staff may include the following:

8.3.3.1. Training on preparation of a meeting (including minute taking, preparation of minutes, meeting agenda, distribution of minutes, meeting agenda and other relevant material)

8.3.3.2. Government Record Management (including Malaysian Government Filing system)

8.3.3.3. Training related to financial management in the Malaysian Government

8.3.3.4. NMRR registration training

8.3.3.5. MREC SOP training

8.3.3.6. Review of the Malaysian Guidelines for Good Clinical Practice, Ministry of Health Malaysia

8.3.4. Members and Secretariat select training that is of interest and submit applications for training to Secretary.

8.3.4.1. Secretary compiles information on selected training and forwards application for endorsement of MREC Chairperson. No endorsement is need for training identified for Chairperson.

8.3.5. Secretary forwards the endorsed application to NIH Secretary for processing of approval and financing.

8.3.6. MREC members, Secretary and/ or Secretariat attend approved training. In the event an individual is not able to attend for reasons accepted by the MREC Chairperson, a replacement shall be nominated as soon as possible for consideration of the approving authorities.

8.3.7. MREC members, Secretary and /or Secretariat records training attended for the year in a **WS 1-3-1**. This is done by 31st December of each year. Secretary and/ or Secretariat files in the relevant personnel file.

8.3.8. Any MREC member who has completed training, shall brief other members on the training attended.

8.3.9. MREC Members, Secretary and Secretariat may also submit educational materials and articles to the Secretary for distribution to all members.

8.3.10. MREC members, Secretary and Secretariat submit application for reimbursement of accommodation, transportation and travelling allowances, as well as other approved expenses, if any, as per standard official procedure.

8.4. **Training records**

8.4.1. After training, MREC members, Secretary and Secretariat record details of training they have attended in **WS 1-3-1** and submits copies of any supporting documents such as certificate of attendance, to Secretary for verification of training attended irrespective of funding source.

8.4.2. MREC Members, Secretary and secretariat make a copy of completed form for personal record.

8.4.3. Secretariat keeps original **WS 1-3-1** and copies of the supporting documents in the relevant MREC personnel file.

9. REFERENCES

9.1. World Health Organization, Operational Guidelines for Ethics Committees That Review Biomedical Research, 2000.

9.2. International Conference on Harmonization, Guideline on Good Clinical Practice (ICH GCP) 1996.

9.3. Ministry of Health Malaysia, Malaysian Guidelines for Good Clinical Practice, 2011.

9.4. The Declaration of Helsinki.

9.5. The Belmont Report, 1979.

9.6. International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), 2002.

10. APPENDIX

Standard Operating Procedure
Independent Expert

Document no.:	SOP 1-4
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REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Initials of Member Secretary
0	All	01/03/2011	Version 1.0, first issue	G.K.
1	All	14/11/2014	Version 2.0, new format with additional information	G.K.
2	7.1, 7.5	04/07/2016	Appointment & term of Independent Expert	G.K.

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1. PURPOSE

The purpose of this section is to provide procedures for engaging the expertise of a professional as an Independent Expert (IE) to the MREC to provide scientific advice on the approval of new studies, amendments of approved studies.

2. SCOPE

If the Chairperson or the MREC determines that a study will involve procedures, technologies or knowledge that is not within the area of expertise of the MREC members, the Chairperson may appoint individuals with relevant expertise to assist or provide advice. Appointment of an Independent Expert is for 1 year and is automatically terminated at the end of appointment term Independent experts shall provide scientific advice on new research submitted to MREC for review and approval as well as approval of amendments of approved research. Designation/ assignment/ selection of an IE is study/ amendment specific.

3. ABBREVIATIONS

CV	*Curriculum vitae*
IE	Independent Expert
MREC	Medical Research & Ethics Committee
NMRR	National Medical Research Register

4. GLOSSARY

Term	Definition
Independent Expert (IE)	An expert who gives advice, comments and suggestions upon review of study protocols with no affiliation to the institutions or investigators proposing the study protocols.

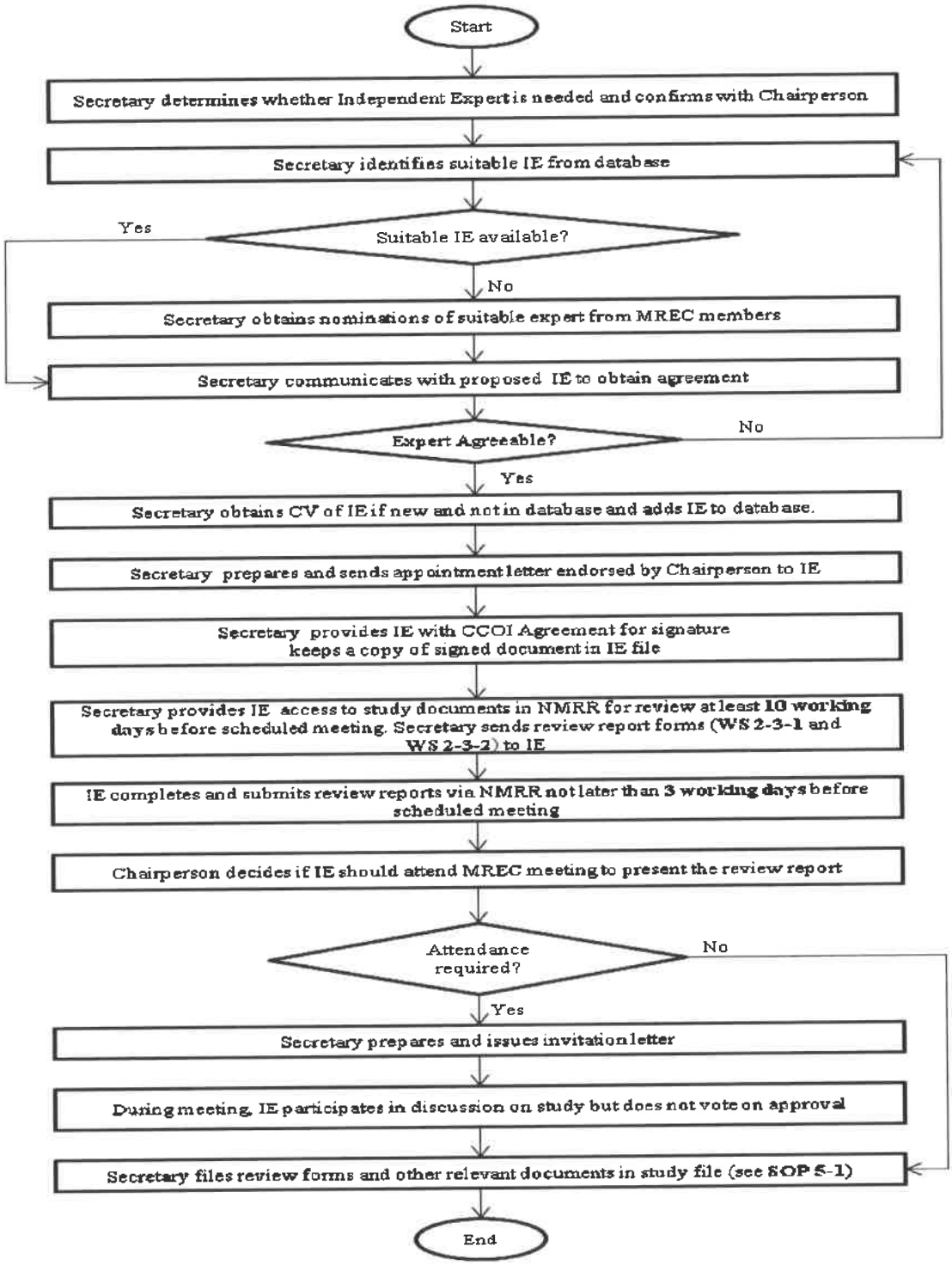
5. REQUIRED AND RELATED DOCUMENT

#	Document Title
1.	**SOP 2-3** : Full board Review
2.	**SOP 5-1 :** Maintenance, Archival and Disposal of Study and Non-Study Files
3.	**WS 1-2-3**: Agreement on Confidentiality and Conflict of Interest for Independent Experts to MREC
4.	**WS 2-3-1:** Review report for Research Protocols involving human subjects
5.	**WS 2-3-2:** Review report for Patient Information Sheet (PIS)

6. PROCEDURE

Step #	Process	Responsibility
1.	Determines whether Independent Expert is needed when study is being scheduled for panel meeting.	Chairperson, MREC Members
2.	Identify suitable IE from list. If a suitable IE is identified, proceed to step 8.	Secretary, Chairperson
3.	If none suitable, obtains nominations of suitable expert from MREC members.	Secretary, Chairperson, MREC Members
4.	Communicates with the proposed IE to obtain agreement	Secretary
5.	If expert agreeable, obtains *curriculum vitae* of IE. Add IE to list. Proceed to step 6. OR If expert disagrees, go back to step 3.	Secretary
6.	Prepares and sends appointment letter endorsed by Chairperson to IE	Secretary
7.	Provides IE with CCOI Agreement (**WS 1-2-3**) for signature and keeps a copy of signed document in IE file	Secretary
8.	Provides IE access to study documents in NMRR for review. Sends review report forms **(WS 2-3-1, WS 2-3-2)** to IE.	Secretary
9.	Completes and submits review reports via NMRR within a timeframe determined by the Secretary. The time frame is determined on case-to case basis based on the urgency and type of review.	Independent expert, Secretary
10.	Decides if IE should attend the MREC meeting to present the review report • If IE required to attend meeting, Secretary prepares and issues invitation letter	Chairperson, Secretary
11.	During meeting, participates in discussion on the study but does not vote on approval	Independent expert
12.	Files review forms and other relevant documents in study files (**see SOP 5-1**).	Secretary

FLOWCHART


Start
Secretary determines whether Independent Expert is needed and confirms with Chairperson
Secretary identifies suitable IE from database
Suitable IE available?
Yes
No
Secretary obtains nominations of suitable expert from MREC members
Secretary communicates with proposed IE to obtain agreement
Expert Agreeable?
No
Yes
Secretary obtains CV of IE if new and not in database and adds IE to database.
Secretary prepares and sends appointment letter endorsed by Chairperson to IE
Secretary provides IE with CCOI Agreement for signature
keeps a copy of signed document in IE file
Secretary provides IE access to study documents in NMRR for review at least 10 working days before scheduled meeting. Secretary sends review report forms (WS 2-3-1 and WS 2-3-2) to IE
IE completes and submits review reports via NMRR not later than 3 working days before scheduled meeting
Chairperson decides if IE should attend MREC meeting to present the review report
Attendance required?
No
Yes
Secretary prepares and issues invitation letter
During meeting, IE participates in discussion on study but does not vote on approval
Secretary files review forms and other relevant documents in study file (see SOP 5-1)
End

7. DETAILED INSTRUCTIONS

7.1. Chairperson/ Deputy Chairperson/ MREC member may suggest names of potential Independent Experts as and when the need arises based on the need of certain subject matter experts. This may be dependent on the therapeutic area of the research submissions received by MREC.

7.2. Chairperson/ Secretary communicates with proposed IE to obtain agreement to provide consultation

7.2.1. If IE agree, Secretary does the following:

7.2.1.1. Obtain *Curriculum vitae*

7.2.1.2. Prepares appointment letter signed by Chairperson.

7.2.1.3. Sends appointment letter to IE together with copy of Confidentiality / Conflict of Interest Agreement (**WS 1-2-3**) for signature. IE sends signed copy of Agreement to Secretary.

7.2.1.4. Keeps copy of the signed Confidentiality / Conflict of Interest Agreement in IE file

7.3. The appointment term for an Independent Expert is indefinite (subject to clause 7.5)

7.4. Secretary creates/ updates a list of independent experts (Independent Expert Database) containing the following information of each expert:

7.4.1. Name and Title

7.4.2. Contact information:, email address, telephone number

7.4.3. Area of expertise (refer to list in NMRR)

7.5. Withdrawal Termination of Appointment

7.5.1. IE may withdraw from being an IE at any time by indicating his decision to the Secretary/ Chairperson. Secretary records this in personnel file together with the reason for discontinuation of appointment.

7.5.2. IE's appointment may also be terminated by MREC at any time. A letter of termination of appointment will be issued by the Chairperson. A copy of this letter will be recorded in the personnel file.

8. REFERENCES

None

9. APPENDIX

None