Standard Operating Procedure
Full Board Review

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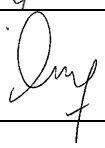
REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Signature of MREC 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	8.2.2, 8.2.3	12/06/2015	Version 2.0, Review of study in the case in the case on no reviewer	
3	8.6.4.5	12/06/2015	Version 2.0, Clarification on appeal request	
4	8.3.2	10/08/2015	Version 2.0, revised statement on requirement from non-primary reviewers to review studies	
5	8.5.8, 8.5.10, 8.5.11. 8.5.12	10/08/2015	Version 2.0, removed statement on Chairperson overriding vote and added statement on Chairperson deferring decision after meeting	
6	8.2 and 8.9	04/04/2016	Version 2.0, Clarified statement on relooking decision made after meeting. Added statement on	

			review of independent expert and medical Reviewer expert	
7.	8.5, 8.7.2	10/10/2018	Version 3.0, added section on Quorum Requirements and Meeting Attendance. Clarified statements on appeal process after disapproval.	
8.	All	25/11/2022	Version 3.1, updated clarification due to new NMRR system.	
9	All	07/11/2025	Version 4.0, simplified and updated to clarify contradicting statement in the SOP.	

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1. PURPOSE

This standard operating procedure (SOP) describes the initial review conducted by the Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia, of research involving human subjects.

2. SCOPE

This SOP applies to the review and assessment of all research conducted by MOH researchers or other researchers using MOH facilities and resources. Decision on approval will adhere to the Malaysian Guidelines for Good Clinical Practice.

3. ABBREVIATIONS

GCP	Good Clinical Practice
ICH-GCP	International Conference on Harmonization – Good Clinical Practice
IE	Independent Expert
MREC	Medical Research & Ethics Committee
MOH	Ministry of Health
NIH	National Institute of Health
NMRR	National Medical Research Register
PIS	Patient Information Sheet
SOP	Standard Operating Procedure

4. GLOSSARY

Term	Definition
Independent Expert	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.
Initial review	The first-time study is reviewed by the MREC. Preliminary online review of study package via NMRR is part of this initial review
Study Package	All documents submitted through NMRR for the review of a study.
No more than Minimal risk	The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
Minor increase over minimal risk	The probability of the occurrence of a low-severity adverse event that is completely reversible or the likelihood of serious harm occurring is low
More than minor increase over minimal risk	The high probability of occurrence of an adverse event that is serious and prolonged or permanent
Minor modifications/minor revision	Modifications or further information that by themselves do not cause more than minor increase over minimal risk
Major modifications/ major revision	Modifications or further information that by themselves cause more than minor increase over minimal risk

5. REQUIRED AND RELATED DOCUMENT

#	Document Title
1.	**SOP 1-1**: Authority and Membership
2.	**SOP 1-4:** Independent Expert
3.	**SOP 2-6:** Review of Resubmission
4.	**SOP 4-1:** Preparation of Agenda, Meeting Procedures and Minutes
5.	**SOP 4-3:** Communication Records
6.	**TP 2-3-1**: Approval letter
7.	**TP 2-3-2:** Disapproval letter
8.	**TP 2-3-3:** Modification letter
9.	**TP 2-3-4:** Termination of Study Application letter
10.	**WS 2-3-1:** Review report for Research Protocols involving human subjects
11.	**WS 2-3-2:** Review report for Patient Information Sheet (PIS)
12.	**WS 2-3-3:** Notification Letter for Investigators to Attend MREC meeting
13.	**WS 2-3-4:** MREC Secretary Study Review Note
14.	**WS 2-3-5:** Minutes of Study Review

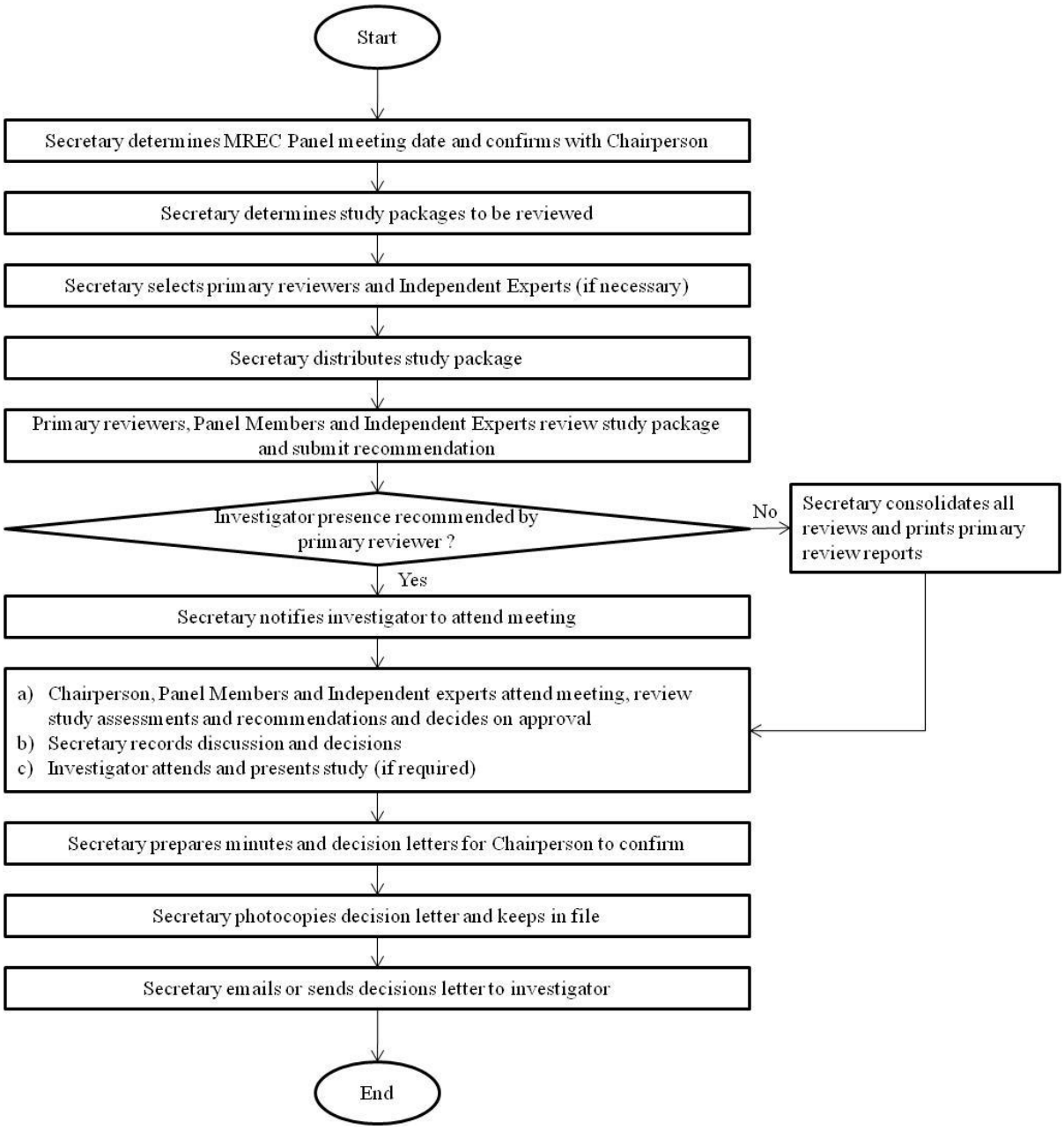
6. PROCEDURE

Step #	Process	Responsibility
1.	Determine the date of the MREC Panel meeting and confirm with the Chairperson.	Secretary
2.	Select study packages from the queued list for review at the scheduled Panel meeting (see Section 8.1).	Secretary
3.	Assign Primary Reviewers and, if required, appoint Independent Expert(s) for each study (see Section 8.2).	Secretary
4.	Distribute study packages to assigned Primary Reviewers, Panel Members, and Independent Experts (if applicable) via NMRR (see Section 8.1).	Secretary
5.	Review assigned study packages and submit comments and recommendations via NMRR. Indicate whether Investigator attendance is required (see Section 8.3).	Primary Reviewers, Panel Members, Independent Experts
6.	(a) Consolidate all reviews in NMRR for each study. (b) Print hard copies of Primary Review reports for the Chairperson. (c) Inform the Investigator to attend the meeting if recommended by the Primary Reviewer (see Section 8.4).	Secretary
7.	(a) Attend the Panel meeting, discuss study assessments and recommendations, and decide on the review outcome (see Section 8.5). (b) Record all discussions and decisions in the meeting minutes. (c) Attend and present the study when requested by the Panel.	Chairperson, Panel Members, Independent Experts (if invited – non-voting); Secretary; Investigator
8.	Prepare meeting minutes and draft decision letters for Chairperson review and confirmation (see Section 8.6).	Secretary

Step #	Process	Responsibility
9.	Communicate decisions to Investigators within the stipulated timelines (see Section 8.7): • Prepare and send Approval Letters (TP 2-3-1) within 10 working days. • Prepare and send Rejection Letters (TP 2-3-2) within 10 working days. • Prepare and send Modification Letters (TP 2-3-3 and WS 2-3-6) within 10 working days. • Archive all signed letters digitally in NMRR in accordance with SOP 5-1.	Secretary
10.	Monitor Investigator responses for modification requests (see Section 8.7.3): • Revised documents to be submitted within 20 working days. • Subsequent responses due within 10 or 5 working days as specified. • Send automated reminders 2 and 5 days before deadlines. • Handle extension requests and manage auto-termination or appeal processes in NMRR.	Secretary
11.	Table all terminated, withdrawn, and disapproved studies for endorsement or record at the next Panel meeting.	Secretary
12.	Maintain and archive all final documents, minutes, and decision letters in accordance with SOP 5-1 and SOP 2-6.	Secretary

7. FLOWCHART

7.1. **Initial full board review**



8. DETAILED INSTRUCTIONS

8.1. Schedule Panel meeting date and distribution of study packages for review

8.1.1 The Secretary determines the date of the MREC Panel meeting in consultation with the Chairperson.

8.1.2 The Secretary selects study packages for full board review from the *Queued List for Full Board* at least **10 working days** before the scheduled meeting. Studies previously identified for full board review will be updated accordingly in the queue.

8.1.3 Study packages are selected on a *first-come, first-served* basis according to the date accepted by the NMRR Secretariat, unless otherwise directed by the Chairperson or Secretary. Normally up to 12 studies will be selected per Panel meeting, unless otherwise decided by the Chairperson or Secretary.

8.1.4 Following selection, the Secretary assigns primary reviewers (see Section 8.2) and distributes meeting notifications and study packages via NMRR and email at least **7 working days** before the scheduled meeting. Investigators whose studies will be tabled are notified of their study status.

8.1.5 The Secretary issues the official call letter to Panel members at least **2 working days** before the meeting (see SOP 4-1).

8.2. Primary reviewers/ Independent Expert/ Medical Reviewer Expert

8.2.1 The Secretary, in consultation with the Chairperson, identifies and confirms **three primary reviewers for each study at least 8 working days** before the meeting:

- one medical member who is a subject-matter expert or Independent Expert (see 8.2.6),
- one scientific or medical member, and
- one non-scientific member.

8.2.2 NMRR sends an email to all Panel members (and any Independent Expert / Medical Reviewer Expert, where applicable) listing the selected study packages.

8.2.3 If a Panel member cannot serve as reviewer for the upcoming meeting, the member must inform the Secretary **at least 9 working days** before the meeting, prior to any assignment. The study will be reassigned to another reviewer if time permits; otherwise, the Chairperson decides whether to retain the study for review or defer it to the next meeting.

8.2.4 If a primary reviewer has a conflict of interest, the reviewer must notify the Secretary within **1 working day** of assignment. The Secretary reallocates the study; if time is insufficient, the Chairperson decides whether to retain or defer review.

8.2.5 Panel members unable to attend the meeting must inform the Secretary before the meeting.
8.2.6 If the sitting Panel lacks a suitable subject-matter expert, the Secretary appoints a Medical Reviewer Expert (from another Panel) or an Independent Expert (from the expert database) as content expert, in addition to the three primary reviewers.

8.2.7 Independent Experts / Medical Reviewer Experts are given at least **5 working days** to complete their review.

8.2.8 If an appointed Independent Expert / Medical Reviewer Expert cannot review, the expert informs the Secretary immediately. The study is re-allocated to another expert if time permits, or deferred to the next meeting.

8.2.9 If no suitable expert is available within either Panel or database, the study is assigned to a member whose expertise most closely matches the subject area.

8.2.10 Independent Experts / Medical Reviewer Experts need not attend the meeting unless specifically requested by the Chairperson or Secretary.

8.3. **Review of Study Package and Submission of Recommendations**

8.3.1 Primary Reviewers

8.3.1.1 Medical and scientific reviewers use WS 2-3-1 for protocol review and WS 2-3-2 for Participant Information Sheet (PIS).
8.3.1.2 Independent Experts / Medical Reviewer Experts (when applicable) use WS 2-3-1 for protocol review.
8.3.1.3 Non-scientific reviewers review PIS using WS 2-3-2.
8.3.1.4 All sections of the review forms must be completed. Reviewers assess risk and benefit (see Section 8.6.6) and recommend approval status and whether the investigator should be interviewed.
8.3.1.5 All primary reviewers and Independent Experts upload their completed review forms to the **Reviewer Rating** page in NMRR not later than **1 working day before** the meeting.

8.3.2 Non-Primary Reviewers

8.3.2.1 Non-primary reviewers may optionally review study packages using WS 2-3-1 and WS 2-3-2.
8.3.2.2 If they do, all sections should be completed and recommendations entered in the Reviewer Rating page by **1 working day before the meeting**

8.4. **Presence of Investigator at Meeting**

8.4.1.1. Primary reviewers inform the Secretary if the Principal Investigator should attend, at least 2 working days before the meeting.

8.4.1.2. The Secretary contacts the investigator to confirm attendance in person or via teleconference. If confirmed, an official notification letter (WS 2-3-3) is sent at least 1 working day before the meeting. If attendance is not possible, the Chairperson decides whether to proceed or defer review. All communications are recorded (see SOP 4.3).

8.5. **Quorum Requirements and Meeting Attendance**

8.5.1 A quorum requires at least **nine (9)** members, including:

- the Chairperson (or Vice-Chair / Alternate Vice-Chair);
- at least one lay member;
- at least one scientific member; and
- at least one member not affiliated with MOH facilities.

8.5.2 A majority decision requires 50 % of attendees plus one.
8.5.3 If quorum is not met, no new application may be decided; other business may proceed if the Chair (or Vice-Chair) and one other member are present.
8.5.4 If quorum is at risk, the Chairperson may (1) invite up to two members from other Panels or (2) postpone and reschedule the meeting.

8.6. **Decision for each study at Panel meeting**

8.6.1 Before the meeting, the Secretary compiles and consolidates all preliminary online assessments and recommendations.
8.6.2 The Chairperson verifies quorum before each study discussion.
8.6.3 Primary reviewers lead the discussion and highlight key issues on scientific value, risk, benefit, and vulnerable subjects.
8.6.3.1 At least one medical/scientific and one non-scientific primary reviewer must be present. If none of the primary reviewers are present, the study is normally deferred unless the Chairperson decides otherwise.
8.6.4 The Secretary displays consolidated reviews, institutional reports, and Independent Expert opinions (if any).
8.6.5 Where applicable, the investigator is interviewed; after the interview, the investigator leaves or the teleconference ends.
8.6.6 Members deliberate on risk, benefit, approval type, and reporting frequency:

- **Risk levels:** minimal risk; minor increase over minimal risk; more than minor increase.
- **Benefit assessment:**
  a) no direct benefit but generalizable knowledge on the condition;
  b) no direct benefit but knowledge benefiting society; or
  c) direct benefit to participants.
- **Decision categories:** approve; minor modifications required prior to approval; major modifications required; disapprove.
- **Progress report frequency:** every 3, 4, 6 or 12 months

8.6.7 The Chairperson records discussion and comments on WS 2-3-4.

8.6.8 Decisions are made by simple majority vote; in a tie, the Chairperson casts the deciding vote. Votes are recorded on WS 2-3-5.
8.6.9 If an Independent Expert's review form is pending, the Chairperson decides whether to (1) withhold communication pending the opinion or (2) proceed without it.
8.6.10 The Secretary prepares meeting minutes and records of decisions (WS 2-3-5) within **10 working days after the meeting.**
8.6.11 If new information arises that justifies reconsideration, the decision may be withheld and the study re-tabled for one additional review before final communication.

8.7. **Communicate Decision to Investigator**

8.7.1 Approved Studies
8.7.1.1 Decision letters (TP 2-3-1) are prepared within **10 working days after the decision made**.
8.7.1.2 Letters state approved documents, approval conditions, frequency of continuing review, investigator obligations, and approval validity (not exceeding one calendar year).
8.7.1.3 The Chairperson's authorised electronic signature image affixed in the letter, to indicate the approval authority.

- Electronically affixed Chairperson's signature by the Secretariat serves as a administrative representation of approval, not as a substitute for decision-making.
- The actual approval decision is granted within the NMRR through documented review and decision entry. The entry is recorded, time-stamped, and auditable within the NMRR system.

8.7.1.4 The decision letter shall be digitally archived in the NMRR system in accordance with SOP 5-1.

8.7.2 Disapproved Studies
8.7.2.1 The Secretary shall prepare the decision letter not later than 10 working days after the decision has been made.
8.7.2.2 The Rejection Letter (TP 2-3-2) shall clearly state the reason(s) for disapproval and outline the appeal process
8.7.2.3 The Chairperson's authorised electronic signature image affixed in the letter, to indicate the approval authority.

- Electronically affixed Chairperson's signature by the Secretariat serves as a administrative representation of disapproval, not as a substitute for decision-making.
- The actual disapproval decision is made within the NMRR through documented review and decision entry. The entry is recorded, time-stamped, and auditable within the NMRR system.

8.7.2.4 The Rejection Letter shall be sent to the Principal Investigator within 10 working days from the decision date.
8.7.2.5 The decision letter shall be digitally archived in the NMRR system in accordance with SOP 5-1.
8.7.2.5 The letter shall state that the decision is final, and any appeal must be submitted as a new study application in NMRR.

8.7.3 Studies Requiring Modifications or Explanations

8.7.3.1 Criteria for minor and major modifications are as defined in Section 4 (Definitions).

8.7.3.2 Modification letters (TP 2-3-3) and WS 2-3-6 are issued within **10 working days after the meeting.**

8.7.3.3 Investigators must submit revised documents to NMRR within **20 working days** of the letter.

8.7.3.4 If further modifications are required, subsequent responses are due within **10 working days** of notification, and any third response within **5 working days.**

8.7.3.5 The Secretary verifies completeness and adequacy of resubmission and routes the study for review as per SOP 2-6.

8.7.3.6 Automated email reminders are sent **2 and 5 days** before deadline.

8.7.3.6.1 Extension requests are considered by the Secretary on a case-by-case basis.

8.7.3.6.2 If no response by deadline, the study is auto-terminated; the system notifies the investigator by email. Appeals are allowed within 7 working days. Documents for resubmission should be uploaded into NMRR within 7 days after reopening. Studies which have been auto terminated more than once will not be entertained for resubmission.

8.7.3.6.3 Requests to reopen a study terminated for > 7 working days will not be considered; a new submission is required.

8.7.3.6.4 Terminated or withdrawn studies are tabled at the next meeting of the original reviewing Panel.

8.7.4 Appeal Procedure for Disapproved Studies

8.7.4.1 Any appeal must be submitted as a new study application in NMRR.

9. REFERENCES

9.1. Malaysian Guideline for Good Clinical Practice, 4th Edition, Ministry of Health, 2018.

10. APPENDIX

None