Standard Operating Procedure
Expedited Review for Initial Approval

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REVISION HISTORY

Rev #	Section	Revision Date	Reason for Revision	Signature of MREC Secretary
0	All	04/07/2016	Version 1.0	
1	All	20/01/2022	Version 2.0 – updates to scope and glossary, latest version of references and guidelines	
2	All	07/11/2025	Version 3.0 – updates to include changes of procedures due to NMRR system change	

TABLE OF CONTENTS

1. PURPOSE

This standard operating procedure describes the criteria for which study can be reviewed through expedited by Chair/Deputy Chairperson/Secretary and MREC Primary reviewer process as well as instructions on management, review and approval of such study

2. SCOPE

This SOP applies to the review and initial approval of studies which have undergone the screening process and initial risk assessment by MREC Secretary/Secretariat.

3. ABBREVIATIONS

MREC	Medical Research and Ethics Committee
NMRR	National Medical Research Register
SOP	Standard Operating Procedure

4. GLOSSARY

Term	Definition
Exemption from MREC approval	An exemption from MREC approval granted based on studies that satisfy the criteria for exemption.
Expedited review by MREC Chairperson	A review process by the MREC Chairperson/Deputy Chairperson for low risk studies that satisfy the criteria.
Expedited review by MREC primary reviewers	A review process by selected primary reviewers who then submit their recommendations for a decision. Studies must satisfy specific criteria of medium risk to qualify for expedited review by primary reviewers.
Minimal risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
Approved, with review by MREC primary reviewers	An ethical approval for a study which has undergone the process of medium risk review by MREC primary reviewers and endorsed by MREC full board.
Approved, with expedited review by MREC Chairperson	An ethical approval for a study which has undergone the process of expedited review by MREC Chairperson/Deputy Chairperson/Secretary

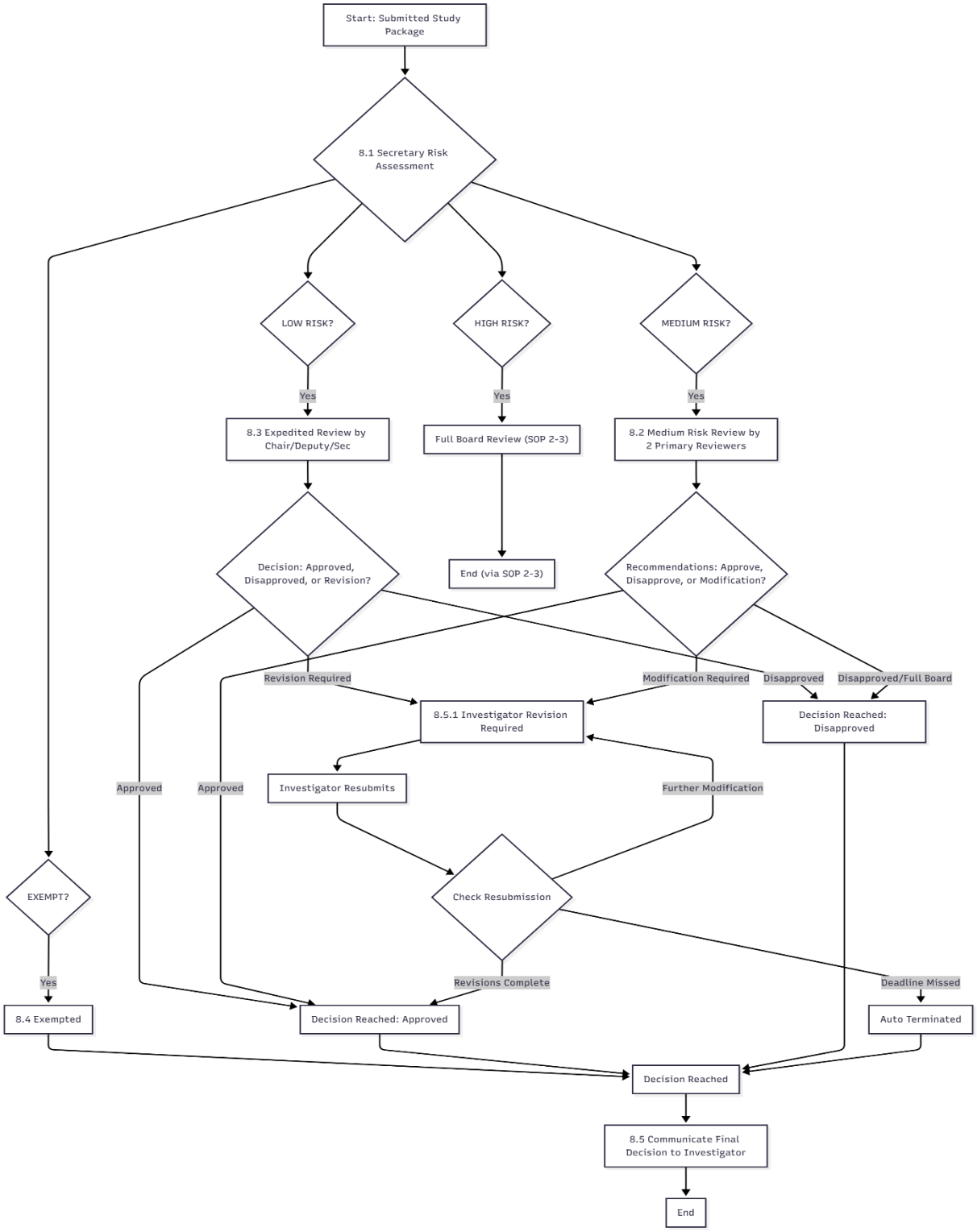
5. REQUIRED AND RELATED DOCUMENT

#	Document Title
1.	SOP 2-1: Research Submission
2.	SOP 2-3: Initial Full Board Review
3.	SOP 2-6: Review of Resubmissions
4.	SOP 2.7: Review of Amendments
5.	SOP 5-1: Maintenance, Archival and Disposal of Study and Non-Study Files
6.	TP 2-3-1: Approval Letter
7.	TP 2-3-2: Disapproval Letter
8.	TP 2-3-3: Modifications Letter
9.	WS 2-3-1: Protocol Review Report
10	WS 2-3-2: PIS Review Report
11	WS 2-4-1: Exempt Protocol/ Patient Information Sheet Review Report
12	WS 2-4-2: Delegated Review Decision

6. PROCEDURE

Step #	Process	Responsibility
1.	Confirms that study qualifies for exemption/expedited review.	MREC Secretary/Secretariat
2.	Assign low risk studies for expedited review by Chairperson	MREC Secretary/Secretariat
3.	Assign medium risk studies for expedited review by primary reviewers and selection of primary reviewers.	MREC Secretary/Secretariat
4.	Conduct expedited review by MREC Chairperson/Deputy Chairperson/Secretary	MREC Chairperson/Deputy Chairperson
5.	Conduct expedited review by MREC primary reviewers	MREC Primary reviewers
6.	Communicate decision to investigator	MREC Secretary/Secretariat

7. FLOWCHART


Start: Submitted Study Package
8.1 Secretary Risk Assessment
LOW RISK?
HIGH RISK?
MEDIUM RISK?
Yes
Yes
Yes
8.3 Expedited Review by Chair/Deputy/Sec
Full Board Review (SOP 2-3)
8.2 Medium Risk Review by 2 Primary Reviewers
Decision: Approved, Disapproved, or Revision?
End (via SOP 2-3)
Recommendations: Approve, Disapprove, or Modification?
Revision Required
Modification Required
Disapproved
Disapproved/Full Board
8.5.1 Investigator Revision Required
Decision Reached: Disapproved
Approved
Approved
Investigator Resubmits
Further Modification
EXEMPT?
Check Resubmission
Yes
Revisions Complete
Deadline Missed
8.4 Exempted
Decision Reached: Approved
Auto Terminated
Decision Reached
8.5 Communicate Final Decision to Investigator
End

8. DETAILED INSTRUCTIONS

8.1 Confirm Risk Assessment

8.1.1 The MREC Secretary/Secretariat completes screening of the submitted study package and performs initial risk assessment in NMRR based on WS 2-1-1 criteria.

8.1.2 Risk Assessment criteria is filled in online via NMRR and is categorized into:

- EXEMPT FROM MREC REVIEW,
- LOW RISK (MINIMAL RISK),
- MEDIUM RISK (MINOR INCREASE OVER MINIMAL RISK), or
- HIGH RISK.

8.1.3 If the study has been categorized as low risk, it will proceed for **EXPEDITED REVIEW**.

8.1.4 If the study has been categorized as medium risk, it will proceed for **MEDIUM RISK REVIEW** by MREC Primary Reviewers and endorsement by full board.

8.2 Medium Risk Review by MREC Primary Reviewers

8.2.1 The Secretary/Secretariat selects **one (1) medical or scientific and one (1) non-medical/non-scientific MREC member** as appropriate to serve as primary reviewers.

8.2.2 Each medium-risk study must have **at least one completed review** before decision issuance.

8.2.3 The primary reviewers are preferably chosen from the non-sitting panel at that time period.

8.2.4 The Secretary then assigns primary reviewers to review a study and informs them of this decision via e-mail. The primary reviewers will then be able to access the relevant study package via the NMRR system.

8.2.5 If a primary reviewer is unable to conduct the review or the primary reviewer has conflict of interest, then conflict of interest has to be declared and member have to inform the Secretary as soon as possible (within 2 days from time assigned) *as it is stated in the email to primary reviewers* so that another member can be selected.

8.2.6 Medical and Scientific reviewers review the study package using online WS 2-3-1 for protocol and WS 2-3-2 for PIS.

8.2.7 Non-scientific reviewer reviews PIS only using online PIS review form (WS 2-3-2).

8.2.8 All sections in both review forms must be completed.

8.2.9 Primary reviewers assess risk and benefit of the study and provide one of the following recommendations:

- Approve without modification
- Minor modifications required
- Major modifications required / disapprove
- Suggest full board review

8.2.10 If modification is required, proceed to Section 8.5.1.

8.2.11 Primary reviewers complete online WS 2-3-1 and WS 2-3-2 review reports into NMRR **within 10 working days** from date assigned.

8.2.12 A completed review (at least 1 completed WS 2-3-1 review report & 1 completed WS 2-3-2 review report) is required before a decision letter is issued by the Secretary/ Secretariat

8.2.13 If the review has not been completed after the deadline for submission of primary reviewers' recommendations, the study will be assigned to another primary reviewer(s)

8.2.14 A decision on the status of the application is based on the recommendations received from the primary reviewers.

8.2.15 In the case of conflict in recommendations/ recommended for disapproval/ recommended to undergo full-board review, the Secretary/ Secretariat may decide/ may refer to the Chairperson/Full Board for verification on the final decision.

8.2.16 Based on recommendation of Primary Reviewers to MREC full board, final decisions are:

- Approved
- Modifications required
- Disapproved
- High Risk Study (to be referred for full board review)

8.2.17 If the decision was major or minor modifications required, to proceed with Section 8.5.1.

8.2.18 If the decision was **APPROVED, WITH REVIEW BY PRIMARY REVIEWERS** then an approval letter will be prepared by the MREC Secretary/Secretariat **within 10 working days** (proceed with Section 8.5.2)

8.3 Expedited review by MREC Chairperson/Deputy Chairperson/Secretary

8.3.1 Studies that have been identified to undergo expedited review by MREC Chairperson/Deputy Chairperson/Secretary will be screened by MREC Secretary/Secretariat for completeness **within 5 working days** of receipt.

8.3.2 MREC Chairperson/Deputy Chairperson/Secretary assesses risk and benefit of the study and record the decision **within 10 working days from the date of assignment**.

8.3.3 If the revision is required, to proceed with section 8.5.1

8.3.4 MREC Chairperson/Deputy Chairperson/Secretary using the WS 2-4-1 will come to the following decision:

- This study is not more than minimal risk (Approved)
- This study is more than minimal risk:
  - Suggest for Expedited Review by Primary Reviewers (Refer to 8.2)
  - Suggest for Full-board Review (Refer to SOP 2-3)
- This study is disapproved (refer to Section 8.5.3)
  This study may be considered for exemption from MREC review; refer to Section 8.4 for confirmation process.

8.3.5 Approval, disapproval, or exemption letters shall be issued **within 10 working days after decision** as per Section 8.5.
8.3.6 Any delay beyond these timelines must be justified and documented by the MREC Secretariat.

8.4 Exempted from MREC review

8.4.1 Studies that have been identified/recommended to be exempted by MREC review will be screened by the Secretary/Secretariat to ensure all documents are complete and the information provided is sufficient.

8.4.2 A study can be exempted from MREC review if it fulfils either one of the following criteria: -

8.4.2.2 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (Mercer University, 2006)
8.4.2.3 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: -

(i)Public benefit or service programs
(ii) Procedures for obtaining benefits or services under those programs
(iii) Possible changes in or alternatives to those programs or procedures
(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

8.4.2.4 Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency

8.4.2.5 Audit with no personal identifier/clinical data

8.4.3 If the decision was **Exempted from MREC** then a decision letter will be prepared and sent by the MREC Secretary/Secretariat within **10 working days** (refer Section 8.5.4)

8.5 Communicate Decision to Investigator

8.5.1. Studies that require Revision, Minor or Major Modifications

8.5.1.1 Secretary/Secretariat prepares signs and sends out:

8.5.1.1.1 **Modification** comments **via NMRR system**, **not later than 10 working days** from the latest decision date. **(For medium risk review by Primary Reviewer)**

8.5.1.1.2 **Automated email** explaining that study requires revision on NMRR system will be sent out when the decision status has been changed to 'revision required'.

8.5.1.2 Investigator must submit revised documents to the NMRR **not later than 20 working days** (for first and second revision) from the date of the automated email.

8.5.1.3 Secretary/Secretariat checks the resubmitted study documents for completeness and ensures that all questions, issues raised have been sufficiently addressed and instruct Secretariat to take appropriate action. The resubmission is reviewed as per **SOP 2-1 (6.2 - submission of modified/revised documents).**

8.5.1.4 In the case of any subsequent modification required by:

8.5.1.4.1 The primary reviewer upon receipt & review of the 1st set of revised study documents, another WS 2-3-6 is sent and investigator must submit the revised documents to NMRR **not later than 10 working days**.

8.5.1.4.2 The Chairperson upon review of the 1st set of revised study documents, another email is sent and investigator must submit the revised documents to NMRR **not later than 5 working days**

8.5.1.5 If the investigator requests for extension of the deadline, the Secretary/Secretariat at discretion will decide on the request and period of extension.

8.5.1.6 An automated e-mail reminder will be sent to the investigator **2 days before the deadline.**

8.5.1.7 Studies with no response after the deadline will be auto terminated in NMRR. An automated email will be sent to the investigator to inform that their submission will not be processed further. Auto terminated studies have to apply a new NMRR ID and will be treated as a new application as per **SOP 2-1**

8.5.1.8 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.

8.5.1.11 Studies that are withdrawn by investigator will be tabled at the next meeting of the Panel that conducted initial review of the study. The Secretary files a copy of the e-mail communication of termination into the study files as per **SOP 5-1.**

8.5.2 Studies that are approved

8.5.2.1 Secretary/Secretariat prepares letters via NMRR system in English and Malay **not later than 10 working days** after the decision approval has been made.

8.5.2.2 Approval letter

8.5.2.2.1 For medium risk review by Primary Reviewers (**TP 2-3-1**) contains at a minimum, a listing of documents reviewed and approved, the frequency of continuing review set by MREC, conditions of approval, obligations of the investigator throughout the course of the study and valid period of approval (not more than one calendar year).

8.5.2.2.2 For expedited by Chairperson (**TP 2-3-5**) contains at a minimum, a listing of site approved, method of data collection approved, the conditions of approval, obligations of the investigator throughout the course of the study and valid period of approval (not more than one calendar year).

8.5.2.3 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 approval, 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.

8.5.2.4 The approval letter will be sent to the investigator **not later than 10 working days** after the approval decision.

8.5.2.5 Decision letter is digitally archived in the NMRR system as per **SOP 5-1**.

8.5.2.6 Secretary tables approved studies for endorsement at the nearest Panel meeting

8.5.3 Studies that are Disapproved

8.5.3.1 Secretary prepares decision letters **no later than 10 working days** after the decision has been made.

8.5.3.2 Rejection letter (**TP 2-3-2**) should state the reason for disapproval and the appeal process.

8.5.3.3 The rejection letter will be sent to the investigator **not later than 10 working days** from the decision date.

8.5.3.4 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.

8.5.3.5 Decision letter is digitally archived in the NMRR system as per **SOP 5-1**.

8.5.3.6 The letter states that the decision is final. Appeals must be submitted as new study application in NMRR.

8.5.3.7 Secretary tables disapproved studies for endorsement at the nearest Panel meeting.

8.5.4 Studies that are Exempted

8.5.4.1 Secretary prepares decision letters **not later than 10 working days** after the decision has been made.

8.5.4.2 Exemption letter (**TP 2-3-6**) should state the reason for exemption from MREC review

8.5.4.3 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 exemption, 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.

8.5.4.4 The exemption letter will be sent to the investigator via NMRR system **not later than 10 working days** from the decision date.

8.5.4.5 Decision letter is digitally archived in the NMRR system as per **SOP 5-1**.

8.5.4.6 Secretary tables exempted studies for endorsement at the nearest Panel meeting

9. REFERENCES

9.1 OHSR (Office of Human Subjects Research), NIH, USA (2005). Code of Federal Regulations (CFR), Title 45 Public Welfare, Part 46 Protection of human subjects.

9.2 FDA 45 CFR 46.101(b)(4)

10. APPENDIX

None