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Standard Operating Procedure
Preparation of Agenda, Meeting Procedures and Minutes

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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.

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1. PURPOSE

This standard operating procedure describes the required activities for the preparation, management and documentation of MREC meetings.

2. SCOPE

This SOP applies to both MREC Panel and business meetings. All personnel involved in preparation, management and documentation of the MREC meetings should be aware of the requirements of this SOP.

3. ABBREVIATIONS

MREC	Medical Research and Ethics Committee
NMRR	National Medical Research Register
SAE	Serious Adverse Events

4. GLOSSARY

Term	Definition
Quorum	A quorum shall consist of at least 50% or 5 members (including the Chairperson) of the attending panel, whichever is less. At least one member whose primary interest is in medical science, at least one member whose primary area of interest is in non-medical / non-scientific areas (layperson) and at least one member independent of the MOH.

5. REQUIRED AND RELATED DOCUMENTS

#	Document Title
1.	SOP 2-3: Initial Full Board Review
2.	SOP 5-1: Maintenance, Archival and Disposal of Study and Non-study Files
3.	TP 4-1-1: Template for Panel Review Meeting Call Letter to MREC members
4.	TP 4-1-2 : Template for Minutes of Panel Review Meeting
5.	TP 4-1-3: Template for Business Meeting Call Letter to MREC members
6.	TP 4-1-4 : Template for Minutes of MREC Business Meeting
7.	WS 4-1-1 : List of projects to be Reviewed

6. PROCEDURE

6.1. Panel Review Meeting

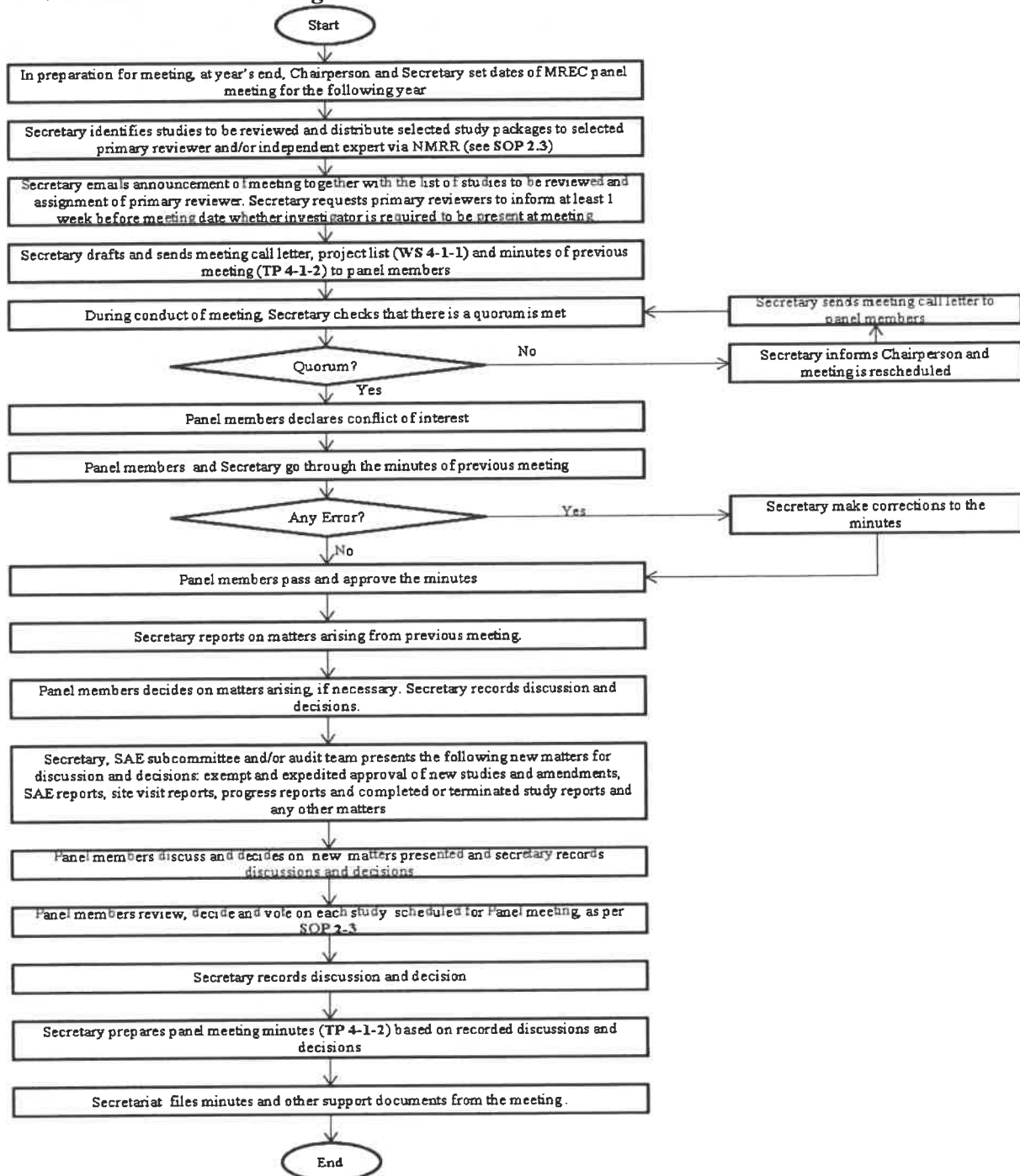
Step #	Process	Responsibility
	Preparation for meeting	
1.	At year's end, set dates of MREC Panel meeting for the following year	Secretary, Chairperson
2.	Identify studies to be reviewed and distribute selected study packages to selected primary reviewer and/or independent expert via NMRR (see SOP 2.3).	Secretary
3.	Emails announcement of meeting together with list of studies to be reviewed and the assignment of primary reviewers. Requests primary reviewers to inform at least 2 working days before meeting date whether investigator is required to be present at meeting	Secretary
4.	Drafts and sends meeting call letter (TP 4-1-1), project list (WS 4-1-1), and minutes of previous meeting (TP 4-1-2), to Panel members.	Secretary
	Conduct of meeting	
5.	Checks that there is quorum. If there is no quorum, inform Chairperson and meeting is rescheduled.	Secretary
6.	Declares conflict of interest.	Panel members
7.	Go through minutes of previous meeting a) If no error, pass and approve the minutes. b) If there is error, make corrections to the minutes.	Panel members, Secretary
8.	Reports on matters arising from previous meeting.	Secretary
9.	Decides on matters arising, if necessary. Secretary to record discussions and decisions.	Panel members
10.	Presents following new matters for discussion and decision: exempt and delegated approval of new studies and amendments, SAE reports, site visit reports, progress reports, completed or terminated study reports, and any other matters.	Secretary, SAE subcommittee, Audit team
11.	Discuss and decide on new matters presented. Secretary to record discussions and decisions.	Panel members
12.	Review, decide and vote on each study scheduled for Panel meeting, as per SOP 2-3.	Panel members
13.	Records all discussion and decision	Secretary

Preparation of minutes of meeting		
14.	Prepares panel meeting minutes (TP 4-1-2) based on recorded discussions and decisions.	Secretary
15.	Files meeting minutes and other support documents from the meeting.	Secretary
16.	Sends minutes to members	Secretary

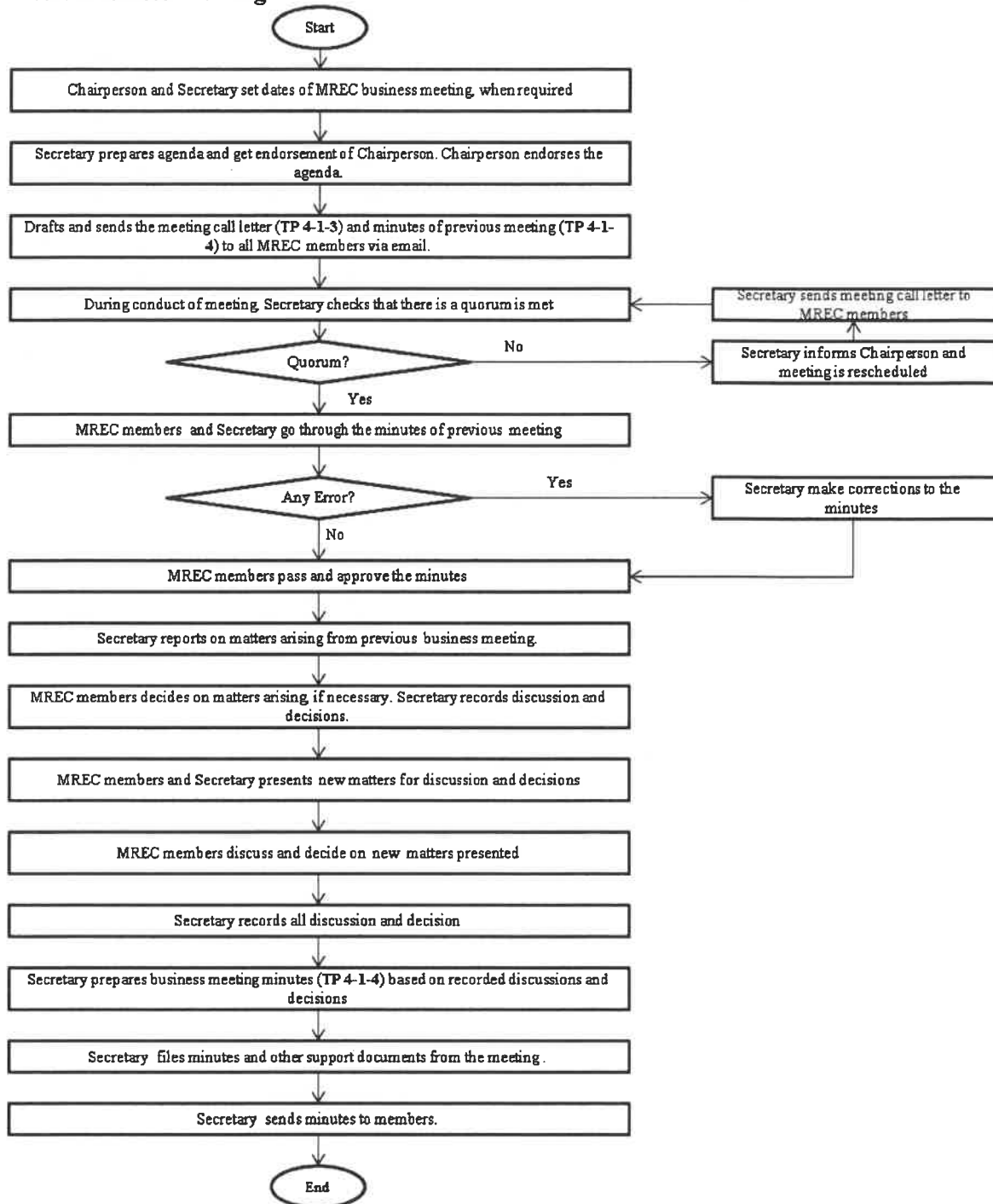
6.2. Business Meeting

Step #	Process	Responsibility
Preparation for Meeting		
1.	Set dates for MREC business meeting when required	Secretary, Chairperson
2.	Prepares agenda and get endorsement of Chairperson	Secretary
3.	Endorses agenda	Chairperson
4.	Drafts and sends the meeting call letter (TP 4-1-3) and minutes of previous meeting (TP 4-1-4) to all MREC members via email.	Secretary
Conduct of Meeting		
5.	Checks that there is quorum. If there is no quorum, inform Chairperson and meeting is rescheduled.	Secretary
6.	Go through minutes of previous meeting c) If no error, pass and approve the minutes. d) If there is error, make corrections to the minutes.	MREC members, Secretary
7.	Reports on matters arising from previous business meeting.	Secretary
8.	Decides on matters arising, if necessary. Secretary to record discussions and decisions.	MREC members
9.	Presents new matters for discussion and decision	MREC members, Secretary
10.	Discuss and decide on new matters presented	MREC members
11.	Records all discussion and decision	Secretary
Preparation of Minutes		
12.	Prepares meeting minutes (TP 4-1-4) based on recorded discussions and decisions.	Secretary
13.	Files meeting minutes and other support documents from the meeting.	Secretary
14.	Sends minutes to members	Secretary

7. FLOWCHART
 7.1. Panel Review Meeting



7.2. Business Meeting



8. DETAILED INSTRUCTION

8.1. Panel Meeting

8.1.1. Preparation for Panel meeting

- 8.1.1.1. Before end of December of the current year, Secretary proposes the number of panels and the dates of MREC Panel meetings for the following year, and confirms with the Chairperson. Upon confirmation, the dates will be posted on the MREC and NMRR websites before the start of the following year.
- 8.1.1.2. The Secretary, in consultation with the Chairperson as necessary, drafts the meeting call letter (TP 4-1-1) and list of projects to be reviewed (WS 4-1-1).
- 8.1.1.3. Secretary selects primary reviewers and/or independent experts. Secretary distributes selected study packages to the primary reviewers and/ or independent experts via NMRR before scheduled meeting (see SOP 2-3).
- 8.1.1.4. Secretary emails preliminary announcement of meeting, list of studies and assigned primary reviewers to Panel members at 7 working days before meeting date.
- 8.1.1.5. Panel members are reminded to inform the Secretary if they are unable to attend the meeting. If the Secretary notes that a quorum may not be met for the meeting, Secretary consults with the Chairperson for the next course of action.
- 8.1.1.6. Primary reviewers inform Secretary at least 2 working days before meeting date whether investigators need to be present at meeting.
- 8.1.1.7. Secretary emails meeting call letter (TP 4-1-1), previous minutes of meeting (TP 4-1-2) and list of projects to be reviewed (WS 4-1-1) to panel members at least 1 working day before scheduled meeting.

8.1.2. Conduct of Panel meeting

- 8.1.2.1. Prior to the commencement of meeting, Secretary checks that a quorum is present for the conduct of the meeting and informs the Chairperson if there is no quorum. Meeting cannot proceed without a quorum and should be rescheduled.
- 8.1.2.2. Panel members declare any conflict of interest and secretary records any declaration. Record(s) should at a minimum include name of member, NMRR ID of study where there is conflict, type/ reason of conflict, and decision of meeting on action to be taken.
- 8.1.2.3. During the meeting, secretary records the following items:
 - 8.1.2.3.1. Attendance of MREC panel members (members present and absent; presence of guest/observers, independent experts)
 - 8.1.2.3.2. Time meeting commenced and adjourned;
 - 8.1.2.3.3. Names of Investigators present for the meeting (present, teleconference, videoconference)- If applicable;
 - 8.1.2.3.4. List of declared conflicts of interest;

- 8.1.2.3.5. Corrections of previous meeting minutes;
- 8.1.2.3.6. A summary of discussions and decisions on all items in the meeting agenda.
- 8.1.2.3.7. A summary of discussions and decisions including number voting for approval or disapproval of a study on studies reviewed. The reason for requiring changes or rejecting a study is recorded as well.
- 8.1.2.4. Panel members go through the minutes of the previous meeting and report any corrections to be made.
- 8.1.2.5. Two Panel members who were present in the previous meeting propose and second the approval of the minutes. Sitting panel then approves the minutes.
- 8.1.2.6. Secretary presents the following matters for endorsement by the Panel members.
 - 8.1.2.6.1. Exempt and delegated approval of new studies
 - 8.1.2.6.2. Exempt and delegated approval of amendments
 - 8.1.2.6.3. Completed/terminated study reports
 - 8.1.2.6.4. Protocol Deviations
- 8.1.2.7. Panel members conducts review of the following:
 - 8.1.2.7.1. Progress reports of approved studies and renewal of MREC approval
- 8.1.2.8. Member of the SAE subcommittee presents SAE reports (if any). Panel members discuss and decide on actions to be taken if relevant.
- 8.1.2.9. Member of Audit team presents report on site visits (if any). Panel members discuss and decide on actions to be taken.
- 8.1.2.10. Meeting discusses any other matters.
- 8.1.2.11. Meeting discusses and decides on each study scheduled for review as per **SOP 2-3**.

8.1.3. Preparation of meeting minutes

- 8.1.3.1. Secretary prepares the minutes of panel meeting (TP 4-1-2). Preparation of study minutes and communication of decision to investigator is listed in **SOP 2-3**.
- 8.1.3.2. The minutes of meeting are filed as per **SOP 5-1** and distributed to Panel members at the next meeting as stated in section **8.1.1.7** as above.

8.2. Business Meeting

Preparation for meeting

- 8.2.1. Chairperson and secretary set dates for MREC business meeting, when required but not less than twice per year.
- 8.2.2. Secretary discusses with Chairperson on the proposed agenda (including from feedback by members & Secretariat) before the meeting and prepares accordingly.

- 8.2.3. Secretary drafts and sends business meeting call letter (TP 4-1-3) and minutes of previous meeting to all MREC members via email, at least one week before the scheduled meeting date.
- 8.2.4. Members are reminded to inform the Secretary if they are unable to attend the meeting. If the Secretary notes that a quorum may not be met for the meeting, Secretary consults with the Chairperson for the next course of action.

Conduct of meeting

- 8.2.5. Secretary checks that a quorum is present for the conduct of the meeting and informs the Chairperson if there is no quorum. Meeting cannot proceed without a quorum and should be rescheduled.
- 8.2.6. During the business meeting, secretary records the following items:
 - 8.2.6.1. Attendance of MREC members
 - 8.2.6.2. Time meeting commenced and adjourned;
 - 8.2.6.3. Corrections of previous meeting minute;
 - 8.2.6.4. A summary of discussions and decisions on all items in the meeting agenda.
- 8.2.7. MREC members and Secretary go through the minutes of previous business meeting and report any corrections to be made.
- 8.2.8. Two MREC members who were present in the previous meeting propose and second the approval of the minutes.
- 8.2.9. Secretary reports on matters arising from previous business meeting and MREC members decide on the matters, if necessary.
- 8.2.10. Secretary presents the agenda and MREC members discuss and decide on any new matters presented.
- 8.2.11. Secretary records all the discussions and decisions.

Preparation of business meeting minutes

- 8.2.12. Secretary prepares minutes for the business meetings (TP 4-1-4) based on the recorded discussions and decisions.
- 8.2.13. Secretariat files the minutes and other support documents from the meeting as per SOP 5-1.

9. REFERENCES

None



10. APPENDIX

None

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Standard Operating Procedure Emergency Meeting

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REVISION HISTORY

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0	All	04/07/2016	Version 3.0, new format with additional information	G.K.

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1. PURPOSE

This standard operating procedure is to describe the administrative process for preparing for an emergency meeting

2. SCOPE

This SOP applies to MREC emergency meetings. Emergency meetings may be scheduled to discuss on safety / life threatening issues, ethical renewals, study terminations and other study activities that require Full Board review.

3. ABBREVIATIONS

MREC	Medical Research and Ethics Committee
NMRR	National Medical Research Register

4. GLOSSARY

Term	Definition
Quorum	A quorum shall consist of at least 5 members (including the Chairperson) of the attending panel, whichever is less. At least one member whose primary area of interest is in non- medical / non-scientific areas (layperson) and at least one member independent of the MOH.

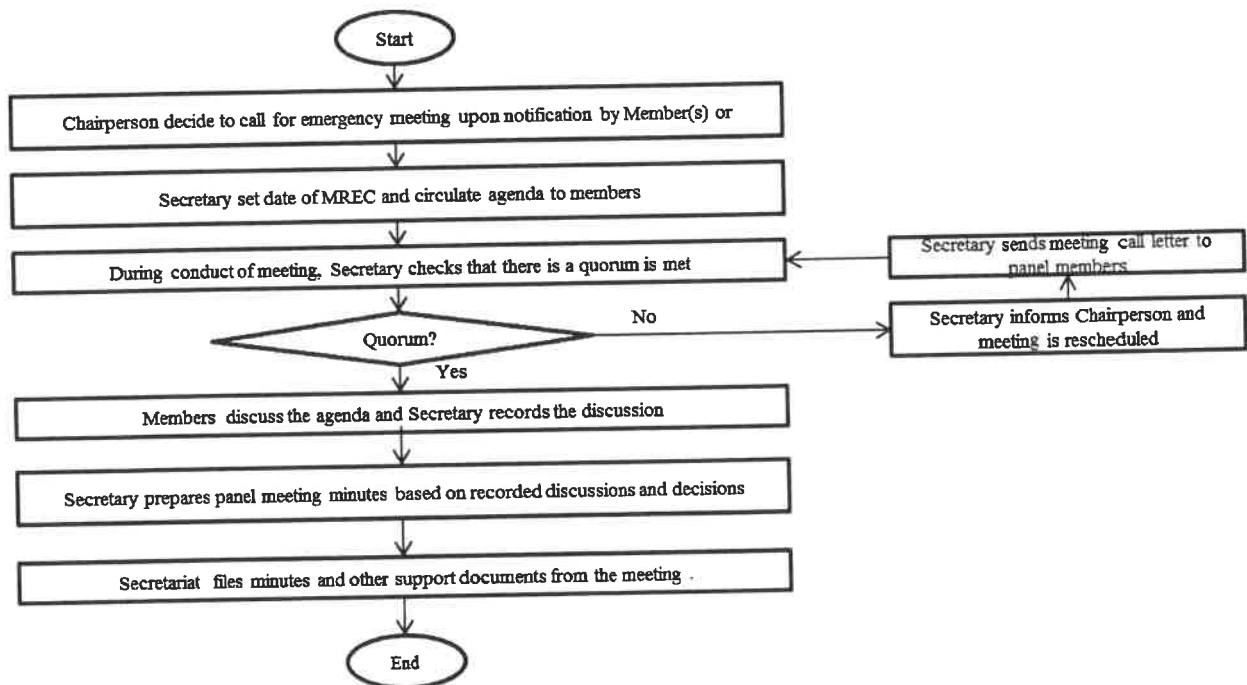
5. REQUIRED AND RELATED DOCUMENTS

#	Document Title
1.	SOP 5-1: Maintenance, Archival and Disposal of Study and Non-study Files

6. PROCEDURE

Step #	Process	Responsibility
	Announce date of emergency meeting	Secretary
1.	Agenda and Meeting Preparation	Secretary
2.	Activities during MREC meeting	Secretary, Chairperson, members
3.	Activities after MREC meeting	Secretary, Chairperson

7. FLOWCHART



8. DETAILED INSTRUCTION

8.1 Announce Date of Emergency Meeting

8.1.1 The Chairperson, upon notification from Secretary and/or Members can decide to call for an emergency meeting for any one or more of the following reasons:

- a. Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety such as occurrence of unexpected serious adverse event(s), public safety or national economy etc.) Life-threatening concerns for the patients continuing in a trial.
- a. Other reasons, as deemed appropriate by the Chairperson.

8.1.2 Secretary contacts and confirms with members on their availability for the emergency meeting before proceeding to scheduling the date, time and venue of the meeting. For the purpose of calling an emergency meeting, contact by telephone or email would be considered as sufficient.

8.1.3 Where necessary/ required upon suggestion by Chairperson, the study Principal Investigator or relevant individuals/ party may be called to be present during the meeting.

8.1.4 The Secretary prepares the agenda for distribution to members containing the information and documents about the matter(s) for which Emergency Meeting is scheduled as well as the reason for calling for the meeting.

8.2 During the Meeting

8.2.1 Secretary records the attendance. A quorum (minimum of 5 including 1 layperson and 1 independent member) must be present for the conduct of the meeting.

8.2.2 Members discuss the agenda and the Secretary records all discussions, votes and decisions.

8.3 Meeting Minute Preparation

8.3.1 Secretary prepares the minutes of the meeting. The minutes of the meeting should include at minimum, but not limited to, the following:

- ❖ Date, Time & Venue
- ❖ Members' attendance List
- ❖ Declaration of conflict of interest
- ❖ IDs of studies discussed, matter of discussion, and decision for the studies.

8.4 Documentation

8.4.1 Secretary records and documents the meeting minutes and relevant letters. (refer to SOP 5.1)

9. REFERENCES

None

10. APPENDIX

None

