

NAMA DOKUMEN:	MEDICAL RESEARCH ETHICS COMMITTEE (MREC) STANDARD OPERATING PROCEDURE FOR DOCUMENTATION AND ARCHIVING	
NOMBOR DOKUMEN:	KOSONGKAN	MUKA KULIT
TARIKH KELULUSAN:	KOSONGKAN	
TARIKH BERKUATKUASA:	KOSONGKAN	
TARIKH KAJISEMULA:	KOSONGKAN	
PENULIS DOKUMEN:	NORASHIKIN MAHMOOD	
DISEMAK OLEH:	MEDICAL RESEARCH ETHICS COMMITTEE	
DILULUSKAN OLEH:	KOSONGKAN	
DISAHKAN OLEH WAKIL PENGURUSAN:	KOSONGKAN	
<p>DOKUMEN INI ADALAH HAK MILIK SEPENUHNYA PUSAT PERUBATAN UNIVERSITI MALAYA (PPUM). <u>SEBARANG SALINAN SEBAHAGIAN ATAU SELURUHNYA DOKUMEN INI TIDAK DIBENARKAN SAMA SEKALI</u> KECUALI MENDAPAT KEBENARAN SECARA BERTULIS DARI BAHAGIAN PENGURUSAN KUALITI, PUSAT PERUBATAN UNIVERSITI MALAYA.</p>		

PUSAT PERUBATAN UNIVERSITI MALAYA

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ABBREVIATIONS

ABBREVIATION	FULL TEXT
GCP	Good Clinical Practice
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MREC	Medical Research Ethics Committee
PI	Principal Investigator
UMMC	University of Malaya Medical Centre

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1.0 INTRODUCTION

Documentation and retention of relevant records are important functions of any IRB/IEC. Proper documentation of all activities and communications are essential as evidence of compliance with local and international guidelines on ethics of research involving human subjects. Malaysian Guideline for GCP section 3.4 states that the IRB/IEC should retain all relevant records for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

2.0 PURPOSE

This SOP describes how UMMC-MREC manages documentation and archival of relevant records of the following activities:

- Preparation, distribution and filing of meeting agenda, minutes of meetings, and other administrative documents and correspondences;
- Proper completion, distribution and storage of submitted study documents and review related communications;
- Processing, storage and disposal of administrative records and documents; and
- Maintenance of archived study documents including their amendments and/or modifications, handling of original documents and copies of documents to protect confidentiality of the documents.

3.0 SCOPE

This SOP is applicable to meeting agenda and minutes, study applications, amendments, modifications, all study documents and correspondences, and all UMMC-MREC administrative correspondences.

4.0 RESPONSIBILITY

The Chair and Deputy Chair of UMMC-MREC are responsible for final approval of documents and correspondence. The Secretary and Secretariat Staff are responsible for the handling, maintenance and archiving of study and administrative documents.

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5.0 MEETING AGENDA

- 5.1 Secretariat staff uses template of meeting agenda (**Appendix 1**) to draft and organize the agenda to be discussed during an MREC meeting.
- 5.2 All the agenda items in template must be completed. The following items are indicated in the agenda:
 - i. Name of all MREC members
 - ii. Name of guests and observers (if any)
 - iii. Name of invitees (Investigators of studies if requested by primary reviewers)
 - iv. Date, time and venue of the meeting
 - v. Confirmation of minutes of last meeting
 - vi. Matters arising
 - vii. Declaration of conflict of interest
 - viii. New studies for consideration
 - ix. Amendments and notifications for consideration
 - x. Expedited approvals of modifications of documents of studies awaiting approval.
 - xi. Expedited approvals of new studies
 - xii. Expedited approvals of amendments of approved studies
 - xiii. Annual study report, study closure report, study progress report, and other notifications
 - xiv. Serious adverse event reports (SAE)
 - xv. Miscellaneous
- 5.3 Agenda items viii, ix, x, xi, xii, xiii and xiv are collected from the iResearch online application system.
- 5.4 The Secretary approves the draft of the meeting agenda by affixing his/her signature.
- 5.5 Secretariat staff places copies of the approved meeting agenda in the members' meeting folders. The original copy is reserved for the MREC Chair.
- 5.6 The Secretary distributes via email, the meeting agenda and related documents to all MREC members not later than 3 working days before the date of meeting.
- 5.7 The Secretary contacts all MREC members, guest, observers and invitees to confirm their attendance at the meeting within 3 working days before the date of meeting.
- 5.8 After the meeting, the Secretariat staff files the original copy of the meeting agenda in the folder 'Meeting Agenda' (PPUM/QSU/300-04/02).

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6.0 MINUTES OF THE MEETING

- 6.1 The Secretary uses template of the minutes of the meeting (**Appendix 2**) to organize and prepare the meeting minutes.
- 6.2 The Secretary takes notes of all final decisions during the meeting, and compiles the Chair's notes.
- 6.3 After the meeting, the decisions on the study discussed in the meeting are transferred by the Secretary into iResearch online application system. The contents of the application status will appear in the online generated letter as follows:
 - i. Approval letter for a study that has been granted full approval during the meeting.
 - ii. Reply for a study which requires modifications/ further action by the investigator.
 - iii. Rejection letter for a study that has been rejected.
- 6.4 The Secretary communicates following decisions by the Chair via the online system to the PI:
 - Expedited approvals of modifications of pending studies
 - Expedited approvals of new studies
 - Expedited approvals of the amendments to approved studies.
- 6.5 The following information must be included in the minutes:
 - i. Date, time and venue of the meeting.
 - ii. Members attendance (members present and absent, with reason if any).
 - iii. Guests and observers' attendance (if any).
 - iv. Chair of the meeting.
 - v. Study details:
 - a. Title
 - b. MREC ID
 - c. Name of PI
 - d. Objectives
 - e. Study period
 - f. Relevant discussion and final decision
 - vi. Time of meeting adjournment.
 - vii. Name and signature of person who prepared the minutes.
 - viii. Name and signature of the Chair to indicate approval.
 - ix. Date of approval.
- 6.6 The Secretary sends draft of the meeting minutes to the Chair for comments and approval.
- 6.7 The minutes are approved by the Chair.
- 6.8 The Secretary sends approved meeting minutes via email to all MREC members at least three working days before the next scheduled meeting.

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- 6.9 Secretarial staff files original copy of the meeting minutes in the folder 'Meeting Minutes' (PPUM/QSU/300-04/03).

7.0 STUDY PROTOCOL COMMUNICATION RECORDS

- 7.1 Communications may be received in the form of letters, official memoranda, emails and phone calls.
- 7.2 The Secretariat Staff sorts all communications received and prepares them for recording and filing.
- 7.3 Secretarial staff records all study-related communication received by MREC in the Communication Logbook (PPUM/QSU/300-04/14). This book is updated as each type of communication is received. The record should contain, but is not limited to, the following:
- i. Date and time of receipt
 - ii. Person receiving the communication
 - iii. MRECID (if applicable)
 - iv. Matters/Issues
 - v. Actions taken (including date and time)
- 7.4 The Secretariat Staff files a copy of communication letters in the 'Letters of Correspondence' folder (PPUM/ QSU /300-04/04).

8.0 ADMINISTRATIVE RECORDS

- 8.1 The Secretariat Staff maintains administrative documents that are not related to specific studies, but are used in daily operations of MREC such as:
- i. Policies (PPUM/QSU/300-04/01)
 - ii. Result Summaries to Board of Management (PPUM/QSU/300-04/05)
 - iii. Audits & Accreditation (PPUM/QSU/300-04/07)
 - iv. Statistics of research conducted (PPUM/QSU/300-04/08)
 - v. Membership (CVs and GCP Certificates, Appointment Letters, Confidentiality Agreements and Conflict of Interest Disclosures and Training Records and Certificates) (PPUM/QSU/300-04/19)
 - vi. Result Summaries to Medical Advisory Committee (PPUM/QSU/300-04/10)
 - vii. Workshop/Course/Training organized by MREC (PPUM/QSU/300-04/12)
 - viii. Related materials and guidelines (GCP, Declaration of Helsinki, SOP, Terms of Reference, etc.) (PPUM/QSU/300-04/13)
- 8.2 These documents are maintained separate from study-related documents.
- 8.3 The Secretariat Staff labels and files administrative documents sequentially.
- 8.4 Only the most recently updated CVs are filed in the Membership folder.

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- 8.5 Signed Confidentiality Agreements and Conflict of Interest Disclosures and training certificates are filed chronologically in every member's individual file.
- 8.6 Training records must be updated as each training certificate is submitted by members for filing.
- 8.7 Title of the documents filed are recorded on the docket page which is located on the file cover.
- 8.8 **Disposal of Documents:**
 - 8.8.1 Meeting agenda, guidelines, references, letters, official memoranda, etc. that have been superseded or outdated are marked "*Ditutup pada (date)*" by Secretariat staff and archived accordingly.
 - 8.8.2 Secretariat staff shreds and permanently deletes redundant copies.

9.0 ONLINE APPLICATION SYSTEM

- 9.1 All types of MREC applications by investigators are made online using the iResearch system.
- 9.2 New study applications are coded as YYYYMMDD-0000, where YYYY represents the year, MM represent the month, DD represents the date of submission and 0000 represents the running serial number for the year. This combination code provides the unique MRECID number for each new application.
- 9.3 Online applications are encoded into the database, which contains the following information:
 - a) MREC ID No.:
 - b) Project/Study title:
 - c) Applicant's name:
 - d) Date of application:
 - e) Date of submission to MREC:
 - f) HOD comments
 - g) Other HOD comments
 - h) Secretariat action:
 - i) Chair/Deputy Chair action:
 - j) Application status (MREC decision):
 - k) Withdraw:
 - l) Action (view application):
 - m) Letter of approval:
 - n) MREC members in attendance:
- 9.4 The following study-related submissions are also made online by investigators and encoded into the database:
 - a) Modifications to documents of studies pending approval
 - b) Amendments to documents of approved studies
 - c) Notifications:
 - i. Study protocol non-compliance report (deviation/violation)

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- ii. Early study termination application
 - iii. Queries and complaints
 - iv. Progress report (including annual study report)
 - v. Study closure report
 - vi. SAE report
 - vii. SUSAR report
 - viii. Clinical Line Listing report
 - ix. Clinical synopsis report
- d) Other submissions that are notified to MREC

9.5 Application and review process

The review process of the application by UMMC-MREC is captured in the online system as follows:

- Acknowledgment by the secretariat staff
- Actions by the secretariat staff
- Replies from applicants
- Actions by the Chair/Deputy Chair (expedited approval/table for meeting/revisions requested/allocation to other MREC members)
- Date of MREC meeting
- Comments of MREC members
- MREC decision (approval/rejection/revision requested)
- Actions by the secretariat staff (after MREC meeting)
- Revisions by applicants
- Actions by the secretariat staff (after revision)
- Actions by the Chair/Deputy Chair on revisions (expedited approval of revision/table for meeting/revisions requested/allocation to other MREC members)
- Communication of decision by online system.

9.6 Maintenance of online application (online system backups)

The online system is based on Software Atempo and is maintained by Information Technology staff of UMMC. Data of all types of MREC applications are stored at the UMMC server located at UMMC data center. The backup process for both database and applications are performed everyday with backup copies kept at UMMC and UM sites. The database backup is performed manually by UMMC staff whereas the application backup is automated. The restoration process of the backup files will be done by UMMC staff if required.

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10.0 MISCELLANEOUS

10.1 **Sorting of archived administrative documents**

10.1.1 The secretariat staff shall perform yearly inventories of miscellaneous administrative documents.

10.1.2 Unnecessary copies are disposed of (see section 7.8 above).

10.2 **Retrieval of documents**

Only authorized MREC secretariat staff, Secretary, and MREC members can retrieve documents either from online system or physical files.

10.3 **Classification of documents as confidential**

10.3.1 Access to confidential documents is restricted to MREC members and Secretariat staff. Limited access can be provided to non-MREC members for legitimate purposes; such non-MREC members will have to submit an application to the Chair.

10.3.2 MREC considers the following as confidential:

- a) Study-related documents including protocols
- b) Meeting agenda
- c) Meeting minutes
- d) Decisions, approval letters, reply letter/notification of MREC decision
- e) Study-related communication.

10.4 **Access to confidential MREC documents**

10.4.1 All MREC members and secretariat staff with signed Confidentiality Agreement and Declaration of Conflict of Interest, have access to MREC confidential documents.

10.4.2 Authorised representatives of MREC members at a stipulated MREC meeting will be given access to documents needed for discussion during the respective meeting.

10.4.3 9.8 Regulatory authorities will be given access to MREC documents for a stipulated period provided in accordance with the authorities' mandate.

10.5 **Reproduction of confidential documents**

The secretariat staff will make the exact number of copies as required for a particular purpose.

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APPENDIX 1

(DATE)

Reference: PPUM/MREC/300-04/02

Elements in reviewing MREC application

In the consideration of a study, particularly clinical trials, the MREC requires that it be conducted in accordance with ICH Harmonised Tripartite Guidelines for Good Clinical Practice (ICH-GCP). In principle, there should be respect for the dignity of the person (the right to information, informed consent and the right to refuse or withdraw from the study) and the research should not over-ride the health, well-being and care of the subject. In this regard, the information given to subjects in the obtaining of informed consent should be in simple layman language. The MREC may request for translations if they think the study population would require that particular language.

The elements of the MREC review would also encompass:

- (1) the scientific worth of the study, as it would be unethical to inconvenience subjects for a futile study,
- (2) the capability and suitability of the investigators to undertake the study,
- (3) the criteria for recruitment of study subjects including the means of contact and recruitment, to ensure no undue coercion or inducement,
- (4) care and protection of subjects, especially that risks to subjects are minimized and also, those risks are reasonable in relation to anticipated benefits,
- (5) special safeguards to protect vulnerable subjects, such as children, pregnant women, the mentally disabled and prisoners,
- (6) provisions for privacy and confidentiality of data obtained,
- (7) cost considerations including coverage of inconvenience, adverse reactions and injuries to subjects, and
- (8) special sensitivities of the community.

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The review process may (and often does) involve an interview of the Principal Investigator.

MEMBERS

Name - Title in UMMC-MREC
Department

INVITEES

Name
Department

Prof. Datuk/Prof./Assoc. Prof./Dr./Mr./Ms.,

UMMC MEDICAL RESEARCH ETHICS COMMITTEE MEETING AGENDA

I refer to the above matter.

A UMMC Medical Research Ethics Committee meeting will be held on:

DATE :
TIME :
VENUE :

The meeting agenda are as follows:

- 1. CONFIRMATION OF PREVIOUS MINUTES**
- 2. DECLARATION OF CONFLICT OF INTEREST**
- 3. MATTERS ARISING**

<u>NO.</u>	<u>MREC ID NO.</u>	<u>PRINCIPAL INVESTIGATOR AND TITLE OF THE STUDY</u>	<u>TIME</u>
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4. (A) NEW APPLICATIONS FOR CONSIDERATION

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To discuss the following applications (Investigator only needs to attend according to the time stated below):

<u>NO.</u>	<u>MREC ID NO.</u>	<u>PRINCIPAL INVESTIGATOR AND TITLE OF THE STUDY</u>	<u>TIME</u>
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(B) AMENDMENTS/NOTIFICATIONS FOR CONSIDERATION

- 5. EXPEDITED APPROVAL TO THE MODIFICATON OF PENDING PROJECTS**
- 6. EXPEDITED APPROVAL TO THE NEW PROJECTS**
- 7. EXPEDITED APPROVAL TO THE AMENDMENTS TO APPROVED PROJECTS**
- 8. STUDY DOCUMENTS NOTIFIED BY THE SECRETARIAT**
 - (A) NOTIFICATION OF ANNUAL STUDY REPORT, STUDY CLOSURE REPORT, STUDY EXTENSION AND STUDY PROGRESS REPORT**
 - (B) OTHER NOTIFICATIONS**
- 9. SERIOUS ADVERSE EVENT REPORTS**
- 10. MISCELLANEOUS**

Thank you, Regards,

“BERKHIDMAT UNTUK NEGARA”

Saya yang menjalankan amanah,

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ROSMAWATI BONTAK

Assistant Secretary
Medical Research Ethics Committee
University of Malaya Medical Centre

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APPENDIX 2



**UNIVERSITY
OF MALAYA
MEDICAL CENTRE**

**MINUTES OF MEDICAL
RESEARCH ETHICS
COMMITTEE MEETING HELD
ON (DATE, TIME, VENUE)**

PRESENT

ABSENT WITH APOLOGIES

INVITEES

1.0	CONFIRMATION OF MINUTES
2.0	DECLARATION OF CONFLICT OF INTEREST
3.0	MATTERS ARISING
4.0	(A) NEW PROJECTS FOR CONSIDERATION
	B) AMENDMENTS/NOTIFICATIONS FOR CONSIDERATION
5.0	EXPEDITED APPROVAL TO MODIFIED PENDING PROJECTS The Chairman/Deputy Chairman had considered and were satisfied with the modifications to the following pending projects and had granted expedited approval through the online system. The Committee endorsed their decisions.

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6.0	EXPEDITED APPROVAL TO AMENDMENTS TO APPROVED PROJECTS The Chairman/Deputy Chairman had reviewed and were satisfied with the following applications for amendments to approved projects, and granted expedited approval through the online system. The Committee endorsed their decisions.
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7.0	The Secretariat notified the following documents received from approved projects and the Committee endorsed the Notification (A) ANNUAL STUDY REPORT, STUDY CLOSURE REPORT, STUDY EXTENSION AND STUDY PROGRESS REPORT
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	(B) OTHER NOTIFICATIONS
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8.0	<u>SERIOUS ADVERSE EVENT REPORTS</u>
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9.0	OTHER MATTERS
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Meeting adjourned at	
PREPARED BY	: NORASHIKIN MAHMOOD Secretary Medical Research Ethics Committee University Malaya Medical Centre
CHECKED BY	:

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PROF. ULUNG DATUK LOOI LAI MENG

Chairman

Medical Research Ethics Committee

University Malaya Medical Centre

DATE

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