**UNIVERSITY OF MALAYA MEDICAL CENTRE**
**MEDICAL RESEARCH ETHICS COMMITTEE**
**SOP IV: DOCUMENTATION AND ARCHIVING**

### 1.0  PURPOSE

This SOP describes how MREC manages documentation and communication of review, such as:

- how the meeting agenda and minutes are prepared, distributed and filed,

- how to ensure proper completion, distribution and filing of written study protocols or review-process related communications,

- how administrative records and documents are processed, stored and disposed of,

- how archived study protocol files are maintained, including their amendments and/or modifications, and

- how to handle original documents and copies of documents in order to protect confidentiality of documents.

### 2.0  SCOPE

This SOP is applicable to meeting agenda and minutes (that are archived for 7 years), applications and/or amendments, modifications and all documents related to the study protocols (that are archived for 3 years after completion of the study) so that these records can be accessible to authorized auditors. This SOP also applies to all handling, distribution and storage of submitted study protocols, MREC documents and correspondence.

### 3.0  RESPONSIBILITY

The Chair and Deputy Chair of 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 protocols and related documents, and administrative documents.

**DETAILED INSTRUCTION**

### 4.0  MEETING AGENDA

| Procedure | Responsibility |
|---|---|
| 4.1  The Secretariat Staff use the template of meeting agenda **(Appendix A)** to draft and organize the agenda to be discussed during an MREC meeting.<br>4.2  All the agenda items must be filled up. The following items shall be indicated in the agenda:<br><br>　i.　Name of MREC members<br>　ii.　Name of guests and observers (if any)<br>　iii.　Name of invitees (Investigators of studies)<br>　iv.　Date, time and venue of the meeting<br>　v.　Confirmation of minutes<br>　vi.　Matters arising<br>　vii.　Declaration of conflict of interest<br>　viii.　New projects for consideration<br>　ix.　Amendments and notifications for consideration<br>　x.　Expedited approvals of modifications of pending projects<br>　xi.　Expedited approvals of new projects<br>　xii.　Expedited approvals of the amendments to approved projects<br>　xiii.　Notifications of annual study report, study closure report and study progress report<br>　　- Other notifications<br>　xiv.　Serious adverse event reports (SAE)<br>　xv.　Miscellaneous | Secretariat staff |
| 4.3  Agenda item viii, ix, x, xi, xii, xiii and xiv are collected from the iResearch online application system. | Secretariat staff |
| 4.4  The Secretary approves the draft of the meeting agenda by affixing his/her signature. | Secretary |
| 4.5  Upon approval, the Secretariat Staff includes copies of the meeting agenda in the members' meeting folders. The original copy is prepared for the MREC Chair. | Secretariat staff |
| 4.6  The Secretary distributes the meeting agenda and related documents via email to all MREC members within 3 working days before the date of meeting.<br>4.7  The Secretary will contact all MREC members, guest, observers and invitees to attend the meeting within 3 working days before the date of meeting. | Secretary |
| 4.8  After the meeting, the Secretariat Staff file the original copy of the meeting agenda in the folder 'Meeting Agenda' (PPUM/QSU/300-04/02). | Secretariat staff |

## 5.0  MINUTES OF THE MEETING

| Procedure | Responsibility |
|---|---|
| 5.1  The Secretary uses the template of the minutes of the meeting **(Appendix B)** to organize the meeting minutes.<br>5.2  The Secretary take notes of all final decisions during the meeting, and also compiles the Chair's notes.<br>5.3  After the meeting, the Secretary transfers the decisions on the study discussed in the meeting into iResearch online application system. The contents of the application status will appear in the online generated letter as follows:<br>    i.  Approval letter for a study that has been granted full approval during the meeting.<br>    ii.  Reply for a study which requires modifications/ further action by the investigator.<br>    iii.  Rejection letter for a study that has been rejected.<br>5.4  The following decisions by the Chair and Deputy Chair are also communited via the online system to the PI:<br>    • Expedited approvals of modifications of pending studies<br>    • Expedited approvals of new studies<br>    • Expedited approvals of the amendments to approved studies<br>5.5  Acknowledgement letter of submission of progress reports (annual study reports and study closure reports), non-compliance reports, SAE reports, queries, complaints and other notifications will be communicated to the PI via the online system. Further decisions by MREC about these submissions will be communicated via emails.<br>5.6  Minutes of the meeting is prepared according to the meeting agenda.<br>5.7  The following information must be included in the minutes:<br>    i.    Date, time and venue of the meeting<br>    ii.    Members attendance (members present and absent, with reason if any)<br>    iii.    Guests and observers attendance (if any)<br>    iv.    Chair of the meeting<br>    v.    Study details:<br>        a.  Title<br>        b.  MREC ID<br>        c.  Name of PI<br>        d.  Objectives<br>        e.  Study period<br>        f.  Relevant discussion and final decision<br>    vi.    Time of meeting adjournment<br>    vii.    Name and signature of person who prepared the minutes<br>    viii.    Name and signature of the Chair to indicate approval<br>    ix.    Date of approval | Secretary |

| Procedure | Responsibility |
|---|---|
| 5.8   The draft of the meeting minutes is sent to the Chair for comments and approval. | |
| 5.9   The Chair approves the minutes by affixing his/her signature. | Chair |
| 5.9   The approved meeting minutes will be sent via email to all MREC members at least three working days before the next scheduled meeting. | Secretary |
| 5.10  The minutes will be presented at the next meeting for confirmation by the members. | Chair |
| 5.11  The Secretariat Staff files the original copy of the meeting minutes in the folder 'Meeting Minutes' (PPUM/QSU/300-04/03). | Secretariat staff |

## 6. STUDY PROTOCOL COMMUNICATION RECORDS

| Procedure | Responsibility |
|---|---|
| 6.1  Communications may be received in the form of letters, official memoranda, emails and phone calls.<br>6.2  The Secretariat Staff sorts all communications received and prepares them for recording and filing.<br>6.3  Study protocol – related communication received by MREC are recorded 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:<br><br>    i.    Date and time of receipt<br>    ii.   Person receiving the communication<br>    iii.  MRECID (if applicable)<br>    iv.  Matters/Issues<br>    v.   Actions taken (including date and time)<br><br>6.4  The Secretariat Staff files a copy of communication letters in the 'Letters of Correspondence' folder (PPUM/ QSU /300-04/04). | Secretariat Staff |

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| **Tarikh Berkuatkuasa:** | **KOSONGKAN** |
| **No. Kajisemula:** | **R00** |

## 7. ADMINISTRATIVE RECORDS

| Procedure | Responsibility |
|---|---|
| 7.1 The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operations of MREC such as:<br>  i.  Policy (PPUM/QSU/300-04/01)<br>  ii.  Result Summary to Board of Management (PPUM/QSU /300-04/05)<br>  iii.  Audit & Accreditation (PPUM/ QSU /300-04/07)<br>  iv.  Statistics of the Research (PPUM/ QSU /300-04/08)<br>  v.  Membership (CVs and GCP Certificates, Appointment Letters, Confidentiality Agreements and Conflict of Interest Disclosures and Training Records and Certificates) (PPUM/ QSU /300-04/09)<br>  vi.  Result Summary to Medical Advisory Committee (PPUM/ QSU /300-04/10)<br>  vii.  Workshop / Course / Training (PPUM/ QSU /300-04/12)<br>  viii.  Related Materials and Guidelines (GCP, Declaration of Helsinki, SOP, Terms of Reference, etc) (PPUM/QSU/300-04/13)<br><br>7.2 These documents are maintained separately from study protocol-related documents.<br>7.3 The Secretariat Staff labels and files administrative documents sequentially.<br>7.4 Only the most recently updated CV are filed in the Membership folder.<br>7.5 Signed Confidentiality Agreements and Conflict of Interest Disclosures and training certificates are filed chronologically under every member's file.<br>7.6 Training records must be updated as each training certificate is submitted by member for filing.<br>7.7 Title of the documents are recorded on the docket file which is located on the file cover.<br><br>**Disposal of documents**<br><br>7.8 Meeting agenda, guidelines, references, letters, official memoranda, etc. that have been superseded or outdated are marked obsolete and archived accordingly.<br>7.9 Redundant copies are shredded and permanently deleted. | Secretariat Staff<br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br>Secretariat Staff |

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| **Tarikh Berkuatkuasa:** | **KOSONGKAN** |
| **No. Kajisemula:** | **R00** |

### 8.0 ONLINE APPLICATION SYSTEM

| Procedure | Responsibility |
|---|---|
| All types of MREC applications are made online using the iResearch system.<br><br>8.1 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 serial number. This combination code provides the unique MRECID number for each new application.<br>8.2 Online applications are encoded into the database, which contains the following information:<br>  a) MREC ID No.:<br>  b) Project/Study title:<br>  c) Applicant name:<br>  d) Date of application:<br>  e) Date of submission to MREC:<br>  f) HOD comments<br>  g) Other HOD comments<br>  h) Secretariat action:<br>  i) Chair/Deputy Chair action:<br>  j) Application status (MREC decision):<br>  k) Withdraw:<br>  l) Action (view application):<br>  m) Letter of approval:<br>  n) MREC attendance:<br>8.3 The following study protocol-related submissions are also made online and encoded into the database:<br>  a) Modifications to studies pending approval<br>  b) Amendments to approved studies<br>  c) Notifications:<br>    i. Study protocol non-compliance reports (deviation/violation)<br>    ii. Early study termination application<br>    iii. Queries and complaints<br>    iv. Progress reports (including annual study reports)<br>    v. Study closure reports<br>    vi. SAE report<br>    vii. SUSAR reports<br>    viii. Clinical Line Listing report<br>    ix. Clinical synopsis report<br>    x. Any other submissions that are notified to MREC<br><br>**Application and review process:**<br><br>8.4 The review process of the application is captured in the online system as follows:<br>  • Acknowledgment by the secretariat<br>  • Actions by the secretariat<br>  • Replies from applicants | Investigator |

| Procedure | Responsibility |
|---|---|
| • Actions by the chair/deputy chair (expedited approval/table for meeting/revisions requested/allocation to other MREC members)<br>• Date of MREC meeting<br>• Comments of MREC members<br>• MREC decision (approval/rejection/revision requested)<br>• Actions by the secretariat (after MREC meeting)<br>• Revisions by applicants<br>• Actions by the secretariat (after revision)<br>• Actions by the chair/deputy chair on revisions (expedited approval of revision/table for meeting/revisions requested/allocation to other MREC members)<br>• Communication of decisions<br><br>**Maintainance of online application (online system back ups):**<br><br>The online system is based on Software Atempo. All data of all types of MREC applications is stored at the UMMC server located at UMMC data center (one server). The backup process for both database and applications is performed everyday with backup copies at UMMC and UM site. The database backup is performed manually by UMMC staff and the application backup is automated. The restoration process of the backup files will be done by UMMC staff. | MREC members, Investigator, Secretary and Secretariat Staff<br><br><br><br><br><br><br><br><br><br><br><br><br>IT personnel |

**9.0 MISCELLANEOUS**

| Procedure | Responsibility |
|---|---|
| **Sorting of archived administrative documents**<br><br>9.1 The secretariat staff shall perform inventories of miscellaneous administrative documents yearly.<br>9.2 Unnecessary copies are disposed of accordingly (see section 7.8 above). | Secretariat Staff |
| **Retrieval of documents**<br><br>9.3 Only authorized MREC secretariat staff, secretary, MREC members can retrieve documents either from online system or physical files. | MREC members, Secretary and Secretariat Staff |

| Procedure | Responsibility |
|---|---|
| **Classification of documents as confidential**<br><br>9.4 Access to confidential documents is restricted by the MREC to members and staff, but limited access can be provided to non-members who have legitimate purpose to access the documents. | MREC members, Secretary and Secretariat Staff |
| 9.5 MREC considers the following as confidential:<br>   a) Study protocols<br>   b) Study protocol-related documents<br>   c) Meeting agenda<br>   d) Meeting minutes<br>   e) Decisions, approval letters, reply letter/notification of MREC decision<br>   f) Study protocol-related communication | MREC members, Secretary and Secretariat Staff |
| **Access to confidential MREC documents**<br><br>9.6 All MREC members and secretariat staff with a signed Agreement and Declaration of Conflict of Interest can have access to MREC confidential documents.<br>9.7 Authorised representative of MREC members at a stipulated MREC meeting will be given access to documents needed for discussion during the respective meeting.<br>9.8 Regulatory authorities will be given access to MREC documents for a stipulated period provided in accordance to the authorities' mandate. | MREC members, Secretary and Secretariat Staff |
| **Reproduction of confidential documents**<br><br>9.9 The secretariat staff will only make the exact number of copies as required. | Secretariat Staff |