

**PUSAT PERUBATAN UNIVERSITI MALAYA**

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

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**ABBREVIATIONS**

<b>ABBREVIATION</b>	<b>FULL TEXT</b>
BOM	Board of Management, University of Malaya Medical Center
CV	Curriculum vitae
FOM	Faculty of Medicine, University of Malaya
GCP	Good Clinical Practice
MREC	Medical Research & Ethics Committee
SAE	Serious Adverse Events
SOP	Standard Operating Procedure
SV	Site Visit
UM	University of Malaya
UMMC	University of Malaya Medical Center

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## PUSAT PERUBATAN UNIVERSITI MALAYA

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### 1.0 PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, amending and storing UMMC-MREC SOPs.

### 2.0 SCOPE

This SOP is applied to any UMMC-MREC SOPs and their amended editions as published and distributed by the UMMC-MREC.

### 3.0 RESPONSIBILITIES

3.1 UMMC-MREC Chair is responsible for ascertaining the need for new SOPs/Guidelines and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including UMMC-MREC members. The UMMC-MREC Chair is responsible for designating the SOP team, chaired by a UMMC-MREC member as assisted by the Secretariat.

3.2 The team shall draft new SOPs and guidelines and amendments to SOPs as needed. The design and format of the SOPs and guidelines are assigned by the UMMC Department of Quality and Clinical Governance and the content shall be written by the SOP team.

3.3 UMMC-MREC members are responsible for UMMC-MREC consensus decision on the proposed SOPs, the outcome of which is approved by the UMMC-MREC Chairman. The Secretariat Staff is responsible for storing and distribution of the SOPs and related documents.

### 4.0 PREPARATION OF THE SOP

#### 4.1 Designing the format, coding and layout

4.1.1 UMMC-MREC SOPs are developed in accordance with UMMC Quality Department *Dokumen Sokongan* (DS) guidelines. All SOPs must be standardized in format for ease of reading, understanding and reference. Every page contains:

- a) Title of the document
- b) Document number
- c) Page number
- d) Effective date

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Commented [GJ1]: What does this asterisk\* mean?

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e) Revision number

4.1.2 An SOP follows the format:

- a) SOP code: follows the SOP on coding of SOPs
- b) Title: which is descriptive of its contents
- c) Purpose: which defines the objective and intended outcome
- d) Scope: which defines the extent of coverage of the SOP and its limitations
- e) Responsibilities: which delineates tasking and accountabilities of SOP implementation
- f) Detailed instruction: which elaborates all the process and procedure in the SOP

4.1.3 Each SOP is alphanumerically coded as "DS – AAAA – BBB", where DS stands for *Dokumen Sokongan*, AAAA is the quality code designated by the UMMC Document Controller, BBB is an alphanumerically code identifying the edition number with major changes in the SOP.

Thus, an SOP is identified with the code DS – 1341 – E01, signifies that this SOP has the quality code 1341, and is the first edition (E01).

4.1.4 Minor changes refer to editorial, grammatical or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have substantial effect on procedures, definitions, requirements and similar considerations.

4.1.5 The SOP is introduced by a cover page laid out as a typical SOP page with a following additional items included:

- a) Name of institution:
- b) Document number:
- c) Page number:
- d) Approval date:
- e) Effective date:
- f) Review date:
- g) Name of author/editor:
- h) Checked by:
- i) Approved by:
- j) Endorsed by Management Representative:

**4.2 Writing and review of new SOPs**

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- 4.2.1 SOPs are issued by the UMMC/MREC in order to facilitate transparent, clear and systematic implementation of its functions.
- 4.2.2 New SOPs may be issued in not less than three-year intervals unless regulations on which these documents are based have significantly changed in the interim.
- 4.2.3 Existing SOPs are reviewed every three (3) years, unless regulations on which these documents are based have significantly changed in the interim.
- 4.2.4 Any amendment or revision must be written and submitted to UMMC Department of Quality and Clinical Governance for registration and shall be endorsed by UMMC Document Controller.
- 4.2.5 A request for amendment or revision is accomplish by filling out the form BK-QSU-007. The UMMC-MREC Chairman is responsible for initial review of the request, procurement of relevant information and recommendation of further action (if any).
- 4.2.6 When the need for a new SOP has been identified and agreed on, UMMC-MREC will organize the writing process whereby the draft will be written by the team deisgnated by the UMMC-MREC Chair. The draft is regarded as a consensus issuance by the team and may be a result of consultatation with other stakeholders prior to completion.

**4.3 Presentation of new/ revised SOP to UMMC-MREC**

- 4.3.1 The draft edition is submitted by the team to the UMMC-MREC.
- 4.3.2 The draft edition will be presented during the regular UMMC-MREC meeting, which is expected to be attended by majority of the members.
- 4.3.3 UMMC-MREC Chairman presents the new/ revised SOP to the UMMC-MREC during this meeting and presides over the deliberation.

**4.4 Decision and approval of UMMC-MREC action on new/ revised SOP**

- 4.4.1 During the meeting, members shall deliberate on the proposed draft and arrive at a consensus action.
- 4.4.2 If a consensus cannot be achieved, the matter is put to a vote.
- 4.4.3 Action can be deferred if recommendation for further amendments or revisions are lodged during the meeting. The UMMC-MREC shall supervise the documentation of requested amendment or revisions and call for a subsequent meeting.
- 4.4.4 Decisions are documented by the secretariat through minutes of the meeting and considered as administrative records and managed accordance with SOP IV: 5.

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4.4.5 The effective date of the SOP is the date of UMMC-MREC meeting to which it is approved indicated by favorable action during the meeting. This date is reflected in the document cover page.

**4.5 Dissemination and storage of new/revised SOP**

4.5.1 An electronic copy of an approved SOP will be published as soon as possible in the UMMC Portal and website to make it immediately available.

4.5.2 One (1) complete originally signed set of current SOPs is maintained by the Secretariat Staff, which can be reproduced as needed.

4.5.3 In case of amended or revised SOP, the old edition will undergo archiving procedures by the Secretariat staff. The word "OBSOLETE" is identified on the old edition, after which it is filed separately from the current edition.

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