

**UNIVERSITY OF MALAYA MEDICAL CENTRE
MEDICAL RESEARCH ETHICS COMMITTEE
SOP V: PREPARING SOPs**

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 versions as published and distributed by the UMMC-MREC.

3.0 RESPONSIBILITIES

3.1 UMMC-MREC Chairman 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 Chairman is responsible for designating the SOP team, chaired by a UMMC-MREC member as assisted by the Secretariat..

3.2 The team shall drafts 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 Procedure (PK) 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
- e) Revision number

4.1.2 An SOP follows the format:

- a) Number and version: 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 PK – 8.1 – AAA – BBB – CCC, where PK stands for Prosedur Kerja, 8.1 is MS ISO 9001 – 2015 clause: Operational Planning and Control, MREC which is the quality code designated by UMMC Document Controller for UMMC-MREC, AAA is a three-digit number corresponding to the SOP chapter, BBB is an alphanumerically code identifying the edition number with major changes in the SOP and CCC is an alphanumerically code identifying the revision number with minor changes in the SOP.

Thus, an SOP is identified with the code PK – 8.1 – MREC – 005 – E01 – R00, signifies that the SOP can be seen in Chapter 5, it is the first edition (E01) and has no revision (R00).

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 PK – 8.1 – MREC – 005 – E01 – R00 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

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 accomplished by filling out the form BK-QSU-007-E07. 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 designated by the UMMC-MREC Chairman. The draft is regarded as a consensus issuance by the team and may be a result of consultation with other stakeholders prior to completion.

4.3 Presentation of new/revised SOP to UMMC-MREC

- 4.3.1 The draft version is submitted by the team to the UMMC-MREC.
- 4.3.2 The draft version 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.
- 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 version will undergo archiving procedures by the Secretariat staff. The word "OBSOLETE" is identified on the old version, after which it is filed separately from the current version.