

 UPM UNIVERSITI PUTRA MALAYSIA	JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA
	4. DOCUMENTATION

4.1 OBJECTIVES

This SOP describes how the JKEUPM manages documentation and communication of review, such as how the minutes of the meetings are to be prepared, used, distributed, and filed; how to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication, how administrative records and JKEUPM administrative documents (exclusive of study protocol files) are processed, stored, or disposed of; how active and inactive or 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.

4.2 SCOPE

This SOP is applicable to regular review panels, to minutes of the meeting, all communication records related to study protocols with JKEUPM approval or undergoing JKEUPM review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least three (3) years after completion of non-clinical trial and 7 years for clinical trial so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, JKEUPM documents, and correspondences.

4.3 RESPONSIBILITIES

The Secretariat Staff, under the supervision of the Member Secretary, has the primary responsibility for study protocol and administrative documentation and archiving of the related documents. The Chair is responsible for final approval of documents.

4.4 MINUTES OF THE MEETING WORKFLOW

Activity	Responsibility
Prepare the template of the Minute s of the Meeting ↓	Secretariat Staff
Prepare draft of Minute s ↓	Secretariat Staff /Member Secretary
Approve the Minutes ↓	Member Secretary, Chair
Store the approved Minutes	Secretariat Staff

4.4.1 Preparation of the template of the Minutes of the Meeting

- 4.4.1.1 The Member Secretary and Secretariat Staff use the **FORMAT OF THE MINUTES OF THE MEETING (DOC 1)** to organize a template of the minutes ahead of the meeting date.
- 4.4.1.2 In case of a special review panel meeting, the **FORMAT OF THE MINUTES OF THE MEETING (DOC 1)** will be adjusted to actual content requirements of the meeting of this type of panel.
- 4.4.1.3 All the relevant identifying information should be filled up such as standard text in the regular sections and relevant study protocol information.
- 4.4.1.4 The draft of the minutes of the meeting is generated as the meeting progresses.
The Member Secretary in charge of documentation notes all board opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.
- 4.4.1.5 The minutes of the meeting is recorded using an audio tape recorder and will be transcribed following the format of the minutes.

4.4.2 Preparation of the draft of the Minutes

- 4.4.2.1 Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.
- 4.4.2.2 The Secretariat Staff in charge of documentation submits a complete draft of the minutes to the Member Secretary within fourteen **(14) working days** after the meeting for content corrections and finalization. The finalized draft is sent to the Chair immediately for approval.
- 4.4.2.3 The following information must be indicated in the minutes:
 - a. Date and venue of meeting
 - b. Members attendance (members present and absent)
 - c. Guests and observers attendance
 - d. Time when the meeting was called to order
 - e. Chair of the meeting
 - f. Items discussed per Meeting Agenda
 - g. Name and signature of the Secretary to indicate that contents have been verified and corrected
 - h. Name and signature of the Chair to indicate approval
 - i. Date of approval by the Chair

4.4.3 Approval of the Minutes

- 4.4.3.1 The Chair approves the draft of the minutes by affixing his/her signature and the date he/she signs the minutes.

- 4.4.3.2 Upon approval of the draft of the minutes, the Secretariat staff transfers contents of the *Conclusions and Recommendations* section (per study protocol discussed) into the forms accordingly.

4.4.4 Storage and Distribution of the Minutes

- 4.4.4.1 The Secretariat Staff files the original copy of the minutes in the Meeting Folder. The minutes will be distributed to all members within **7 working days** before the next full board meeting.
- 4.4.4.2 The minutes will be presented in the next full board meeting for panel approval.

4.5 STUDY PROTOCOL COMMUNICATION RECORDS WORKFLOW

Activity	Responsibility
Sort all communications received and issued by the JKEUPM ↓	Secretariat Staff
Record the details of the communication ↓	Secretariat Staff
Store communication files	Secretariat Staff

4.5.1 Sorting of all communications received and issued by the JKEUPM

- 4.5.1.1 Communications can come in the form of letters, official memoranda, or emails.
- 4.5.1.2 The Secretariat Staff sorts all communications received and prepares them for recording.

4.5.2 Recording of the details of the communication

- 4.5.2.1 The usage of correction pen on all documentation are not allowed. Correction on the documentation should be crossed out. Amendment to the correction should be signed and dated next to the correction.

4.5.3 Storage of communication records

- 4.5.3.1 The Secretariat Staff files a copy of the communication in the study file.
- 4.5.3.2 For SAE Files, the secretariat staff stores the signed serious adverse event/s report in the study protocol file folder.
- 4.5.3.3 The Secretariat Staff then writes in the protocol folder contents index as each communication is filed.

4.6 ADMINISTRATIVE RECORDS WORKFLOW

Activity	Responsibility
Compile administrative documents and/or records ↓	Secretariat Staff
Sort and store documents ↓	Secretariat Staff
Dispose unnecessary copies	Secretariat Staff

4.6.1 Compilation of administrative records

4.6.1.1 The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operations of the JKEUPM such as:

- a. Reference materials and guidelines
- b. Standard Opening Procedures
- c. Communications issued to and received from persons other than principle investigators, on matters that are not related to any study protocols
- d. JKEUPM members and staff files (CVs, Appointment letters, signed LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS (JKEUPM FORM 1.1), TRAINING RECORDS (JKEUPM FORM 1.2), Certificates of training
- e. Forms (uploaded in the RMC website)
- f. Minutes of General Assembly

4.6.1.2 These documents are maintained separately from study protocol-related documents.

4.6.2 Sorting and storage of documents

4.6.2.1 The Secretariat Staff labels and files administrative documents sequentially.

4.6.2.2 Guidelines are filed chronologically.

4.6.2.3 SOP Manuals are filed chronologically.

4.6.2.4 Important communications are filed in the communications folder and recorded chronologically.

4.6.2.5 Members' and staff files are filed according to the name list pasted in the file

4.6.2.6 Signed LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS (JKEUPM FORM 1.1) and training certificates are filed chronologically under member's and staff's file.

4.6.2.7 TRAINING RECORDS must be updated as each training certificate is submitted by the member or staff for filing.

4.6.3 Disposal of unnecessary copies

4.6.3.1 Removed document files are shredded and permanently deleted from electronic and physical files.

4.7 ACTIVE FILES WORKFLOW

Activity	Responsibility
Create a coding system for active files ↓	JKEUPM
Organize the contents of the active study files ↓	Secretariat Staff
Maintain the active study files	Secretariat Staff

4.7.1 Creation of coding system for active study files

4.7.1.1 Active files are study protocols that have been received by the JKEUPM Secretariat and are either undergoing review (full board or expedited) or approved by the respective JKEUPM Panel.

4.7.1.2 All study files are coded as UPM/TNCPI/RMC/1.4.18.2/ JKEUPM-YYYY-000, where UPM/TNCPI/RMC/1.4.18.2 follows the university ISO requirement and YYYY represents the year and 000 represents the number of file.

4.7.1.3 The study file code should appear prominently on the study protocol folder.

4.7.2 Organization of contents of active study files

4.7.2.1 Study files are encoded into the Study Protocol Database.

a. List of documents in the non-clinical study file:

- Form 2.1 (Checklist for Applicants)
- Form 2.3 (JKEUPM application form)
- Proposal
- Executive summary
- Questionnaire (if any) –version English/Malay or Others
- Form 2.4 (Respondent's Information Sheet and Consent) - version English/Malay or Others
- Form 2.5 (Respondent's Information Sheet and Guardian's/Parent's Consent) - version English/Malay or Others
- Supporting document (if any)
- CVs of researcher
- Approval Letter

b. While the following documents in the clinical trial study file:

Compulsory:

- Good Clinical Practice (GCP) certificate
- Investigator's brochure (IB)
- Signed clinical study protocol and amendments
- Sample case report form
- Informed consent form
- Insurance statement
- Subject compensation
- Curriculum vitae and relevant documents of qualification of PI and co-PIs
- Certificates of analysis of investigational products
- Decoding procedures for blinded trials
- Respondent information sheet
- All available safety information
- All questionnaires used

If Applicable:

- Trial Initiation monitoring report
- Advertisement for subject recruitment
- Signed agreement between parties involved
- Shipping records for investigational products
- Pre-trial monitoring report
- Material transfer agreement (MTA)

4.7.2.2 The Secretariat Staff puts study protocol files in file folders upon processing of the submission of the study protocol.

4.7.2.3 Folders are then kept in secure cabinets according to the year and faculty.

4.7.3 Maintenance of study protocol files

4.7.3.1 The Secretariat Staff files all the aforementioned documents in the study folder as they come.

4.7.3.2 The Secretariat Staff stamps the receiving date on all documents before putting them in the folders.

4.7.3.3 All File folders are maintained in the cabinet until the **STUDY FINAL REPORT (JKEUPM FORM 3.2)** is approved by the JKEUPM Panel.

4.7.3.4 The Secretariat Staff maintains Panel Files cabinets under the supervision of the Member Secretary.

4.7.3.5 The pest control activities in the file storage room will be carried out periodically once a year.

4.8 ARCHIVED (INACTIVE/COMPLETED/TERMINATED) FILES WORKFLOW

Activity	Responsibility
Manage completed/inactive /terminated study files ↓	Secretariat Staff
Sort administrative documents to be archived ↓	Secretariat Staff
Establish archived documents retrieval process	Secretariat Staff

4.8.1 Management of Archived (inactive/completed/terminated) study files

4.8.1.1 Archived (Inactive/Completed/Terminated) study files are either:

- a. Study protocols with approved (by the JKEUPM) final reports, or
- b. Approved study protocols declared Inactive by the review panel if no communication is received from study team for a period of twelve months.
- c. Study protocols for initial review with resubmissions beyond 90 days from date of action letter.

4.8.1.2 Upon receipt of **JKEUPM FORM 3.2: STUDY FINAL REPORT**, the JKEUPM panel reviews it in accordance with SOP III.

4.8.1.3 Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

4.8.1.4 All completed study files will be colour coded as red by placing the sticker on the file.

4.8.2 Retrieval of documents

4.8.2.1 Only authorized JKEUPM Secretariat Staff can retrieve documents either from active study files or from the archives.

4.8.2.2 Active or inactive study files can be borrowed, upon written request by the PI or the JKEUPM personnel, and only for room use.

4.9 Confidentiality of study files and JKEUPM documents Workflow

Activity	Responsibility
Classify documents as confidential ↓	JKEUPM
Request access to JKEUPM documents ↓	Members, non-members
Reproduce confidential documents ↓	Secretariat Staff
Maintain log of copies issued	Secretariat Staff

4.9.1 Classification of documents as confidential

4.9.1.1 Access to confidential documents is restricted by the JKEUPM to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.

4.9.1.2 The JKEUPM considers the following as confidential:

- a. Study protocols
- b. Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- c. Meeting Minutes
- d. Decisions, action letters/notification of JKEUPM decision, approval letters
- e. Study protocol-related communications

4.9.2 Access to confidential JKEUPM documents

4.9.2.1 All JKEUPM members and the staff with a signed **JKEUPM FORM 1.1: LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS** can have access to JKEUPM confidential documents upon request.

4.9.2.2 Non-members can access specific documents upon formal request and completion/signing of **JKEUPM FORM 1.4: NON DISCLOSURE OF CONFIDENTIAL INFORMATION AND CONFLICT OF INTEREST**. The form requires the approval of the JKEUPM Chair. Regulatory authorities have full access to JKEUPM files provided it is within said authorities' mandate, and upon reasonable notice to make the files available.

4.9.2.3 All requests for access are recorded by the Secretariat Staff in the LOG OF REQUEST FOR COPIES OF DOCUMENTS (JKEUPM FORM 4.1) before the documents are released.

4.9.3 Reproduction of confidential documents

4.9.3.1 The Secretariat makes only the exact number of copies requested.

4.9.3.2 The recipient signs for the copies requested in the LOG OF REQUEST FOR COPIES OF DOCUMENTS (JKEUPM FORM 4.1) upon receipt of the copies.

4.9.4 Maintenance of log of copies

4.9.4.1 The Secretariat staff ensures the diligent recording of all document copies issued in the LOG OF REQUEST FOR COPIES OF DOCUMENTS [JKEUPM FORM 4.1].

4.9.4.2 This log is filed in a separate folder labelled Log of Copies Issued.

4.10 REVISING SOP WORKFLOW

Activity	Responsibility
Propose to revise the SOP ↓	JKEUPM Member/s
Review, discuss and approve the SOP draft revision in a full board meeting ↓	JKEUPM Member/s
Approve and sign the SOP revision ↓	Chair/DVC
File and distribute the revised SOP ↓	Secretariat Staff
Archive the superseded SOP	Secretariat Staff

4.10.1 JKEUPM Member/s proposes to revise the SOP

4.10.1.1 As the JKEUPM sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical is not considered as substantial; a change in the identifier of an SOP is considered substantial. 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 a substantial effect on procedures, definitions, requirements, and similar considerations.

4.10.1.2 When an SOP is difficult to understand or does not cover what it should, a revision may become necessary. The SOP may be reviewed regularly by the Member Secretary every two years.

4.10.1.3 Secretariat or any member of the board may propose for the revision of the SOPs and submit a written proposal to the Member Secretary.

4.10.1.4 Any proposal for revision must be written and submitted by the Member Secretary/Secretariat to the board for review, approval, coding, and inclusion into the document.

4.10.2 JKEUPM Members review, discuss and approve the SOP draft revision in a full board

meeting

4.10.2.1 When the need for a revision of SOP has been identified and agreed on, a draft will be written by a Secretariat. A draft of the revised SOPs will be discussed by the JKEUPM members. The draft version will be reviewed by the Chair who will submit it to the Deputy Vice Chancellor for Research and Innovation for approval.

4.10.2.2 The Secretariat drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.

4.10.2.3 The Chair submits the drafts to the full board review where the JKEUPM members deliberate on the draft.

4.10.3 The IEC Chair and the VCR shall approve and sign the SOP revision

4.10.3.1 The Chair submits the approved draft to the Deputy Vice Chancellor for Research and Innovation for final approval.

4.10.3.2 The Deputy Vice Chancellor for Research and Innovation approves the revised SOP by signing on the appropriate section of the cover page.

4.10.3.3 The approved revised SOP will be implemented from the date of approval by the Deputy Vice Chancellor for Research and Innovation.

4.10.4 The JKEUPM Secretariat files and distributes the revised SOP

4.10.4.1 Upon approval of Deputy Vice Chancellor for Research and Innovation, the Secretariat distributes the revised SOP to JKEUPM members, updates the electronic SOP manual, and publishes the SOP through the Deputy Vice Chancellor for Research and Innovation website.

4.10.4.2 The Secretariat maintains the originally signed updated SOP manual in the Deputy Vice Chancellor for Research and Innovation office and retains one copy of the originally signed outdated versions.

4.10.4.3 The JKEUPM Secretariat collects the old SOP manuals in exchange of the revised manual.

4.10.4.4 The JKEUPM Secretariat includes the revised SOP in the SOPs manual that is currently used.

4.10.5 The JKEUPM Secretariat archives the superseded SOP

4.10.5.1 The Secretariat archives the superseded version of the SOP in the historical file.

4.10.5.2 Superseded SOPs are clearly marked "superseded" with the year of archiving stamped in the cover page.

4.10.5.3 Outdated SOPs are considered a permanent file.