

Standard Operating Procedures

IV. DOCUMENTATION AND ARCHIVING

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Document History

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Assoc. Prof. Dr. Nor Azwany Yaacob, Assoc. Prof. Dr. Siti Hawa Ali, Prof. Wan Abdul Manan Wan Muda, Dr. Teguh Haryo Sasongko, Assoc. Prof. Dr. Mohtar Ibrahim, Assoc. Prof. Noraida Ramli, Pn. Zawiah Abu Bakar.	01	06/04/2014	First draft
Prof. Dr. Mohd Shukri Othman, Prof. Dr. Nik Hazlina Nik Hussain, Dr. Haslina Taib, Dr. Soon Lean Keng, Mr. Hj. Ismail Hassan and Mr. Mohd Bazlan Hafidz Mukrim.	02	07-09-2015	Second Version – minor changes in forms 4(B), 4(E), 4(L) and 4(O).
Prof. Dr. Hans Amin Van Rostenberghe and Mr. Mohd Bazlan Hafidz Mukrim.	03	10-08-2016	Third Version – administrative changes in forms 4(A), 4(B), 4(C), 4(D), 4(E), 4(F), 4(G), 4(H), 4(I) and 4(L) based on the recommendation made during inspection by BPFK on 12-14 April
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1. Objectives

This Standard of Procedure (SOP) describes how the JEPeM-USM 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 JEPeM-USM 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.

2. Scope

This SOP applies to minutes of the meeting, all communication records related to study protocols with JEPeM-USM approval or undergoing JEPeM-USM 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 the research 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, JEPeM-USM documents, and correspondences.

3. Responsibilities

The Secretariat Staff, under the supervision of the JEPeM-USM Secretary, has the primary responsibility for study protocol and administrative documentation and archiving. The Chairperson/Deputy Chairperson/Panel Chair is/are responsible for final approval of documents. The secretariat staff will be provided with their dedicated workstation and online account. The Member secretary will check the appropriateness, consistency of the contents and all the communications issued to the Principal Investigator. All the above communications will be stamped and signed by the Chairperson/Deputy Chairperson/Panel Chair or the Secretary.

4. Minutes of the Meeting Workflow

ACTIVITY	RESPONSIBILITY
Prepare the template of the Minutes of the Meeting ↓	Secretariat Staff and Secretary
Prepare draft of Minutes ↓	Secretariat Staff and Secretary
Approve the Minutes ↓	Secretary, Member Secretary and Chairperson/Deputy Chairperson/Panel chair
Store the approved Minutes	Secretariat Staff

DETAILED INSTRUCTIONS

4.1. Preparation of the template of the Minutes of the Meeting

- 4.1.1. The Secretary and Secretariat Staff use the **FORMAT OF THE MINUTES OF THE MEETING [JEPeM-USM FORM 4(A)]** to organize a template of the minutes ahead of the meeting date.
- 4.1.2. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.
- 4.1.3. The minutes of the meeting are generated as the meeting progresses. The Secretariat Staff and Secretary in charge of documentation notes all board opinions and specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.

4.2. Preparation of the draft of the Minutes

- 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.
- 4.2.2. The Secretariat Staff in charge of documentation submits a complete draft of the minutes to the Member secretary and Chairperson/Deputy Chairperson/Panel Chair within **fourteen (14) working days** after the meeting for checking, corrections, finalization and approval.
- 4.2.3. The following information must be indicated in the minutes:
 - Date, time and venue of meeting
 - Members attendance (members present
 - Guests and observers attendance (if any)
 - Time when the meeting was called to order
 - Presiding officer

- Items discussed per Meeting Agenda
- Date stamp and signature of person who prepared the Minutes
- Date stamp and signature of the Member Secretary and Chairperson/Deputy Chairperson/Panel Chair to indicate that the contents have been verified and corrected

4.3. Approval of the Minutes

- 4.3.1. The Chairperson/Deputy Chairperson/Panel Chair approves the Minutes by affixing his/her signature and the date the minutes was stamped and signed.
- 4.3.2. Upon approval of the minutes, the contents of the *Conclusions and Recommendations* section (per study protocol discussed) are transferred into either an:
 - APPROVAL LETTER TO THE STUDY PROTOCOL [JEPeM-USM FORM 4(B)], or
 - ACTION LETTER TO STUDY PROTOCOL SUBMISSIONS, RESUBMISSIONS AND AMENDMENTS [JEPeM-USM FORM 4(C)], APPROVAL LETTER TO THE STUDY PROTOCOL AMENDMENT [JEPeM-USM FORM 4(E)], NOTIFICATION LETTER (REQUEST INFORMATION) TO CONTINUING REVIEW APPLICATION, FINAL REPORT, DEVIATION, SAE, SITE VISIT [JEPeM-USM FORM 4(F)], ARCHIVING NOTIFICATION [JEPeM-USM FORM 4(G)], and NOTIFICATION LETTER (UPHOLD APPROVAL TO CONTINUING REVIEW APPLICATION, DEVIATION, SAE, SITE VISIT [JEPeM-USM FORM 4(L)] as the case may be (see Appendices for all forms).

4.4 Storage of the Minutes

- 4.4.1. The Secretariat Staff files the original copy of the Minutes in the Minutes Folder.
- 4.4.2. The Secretariat Staff makes copies of the minutes approved by the Chairperson/Deputy Chairperson/Panel Chair and files a copy in the members' meeting folders.
- 4.4.3. The Minutes approved by the Chairperson/Deputy Chairperson is distributed to the members at least **three (3) calendar days** before the next meeting.
- 4.4.4. The minutes will be presented in the next full board meeting for approval by the full board.
- 4.4.5. **The minutes will be stored in the section of Administrative Documents for at least 7 years.**

5. Study Protocol Communication Records Workflow

ACTIVITY	RESPONSIBILITY
Sort all communications received and issued by the JEPeM-USM ↓	Secretariat Staff
Record the details of the communication ↓	Secretariat Staff
Store communication files	Secretariat Staff

DETAILED INSTRUCTIONS

5.1. Sorting of all communications received and issued by the JEPeM-USM

- 5.1.1. Communications can come in the form of letters, official memoranda, or emails.
- 5.1.2. The Secretariat Staff sorts all communications received and prepares them for recording.
- 5.1.3. Once the completed documents are received, the secretariat staff will digitally signed and locked the document appropriately to ensure the security and full protection of the documents.

5.2. Recording of the details of the communication

- 5.2.1. Study protocol-related communications received by the JEPeM-USM are recorded and updated as each submission is received. The record should contain, but is not limited to, the following:
 - Date Received
 - Study Code
 - Title
 - Principle Investigator
 - Submitting Person
 - Receiving Person
 - Date of Document
 - Type of Submission
 - Content of Submission
 - Mode of Delivery
 - Staff Action
 - Further Action Required

5.3. Storage of communication records

- 5.3.1. Upon completion of the **SUBMISSIONS** the Secretariat Staff files a copy of the communication in the study file.

6. Administrative Records Workflow

ACTIVITY	RESPONSIBILITY
Compile administrative documents and/or records ↓	Secretariat Staff/Members/Chair
Sort and store documents ↓	Secretariat Staff
Dispose unnecessary copies	Secretariat Staff

DETAILED INSTRUCTIONS

6.1. Compilation of administrative records

- 6.1.1 The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operations of the JEPeM-USM such as:
- Reference materials and guidelines [Good Clinical Practice (GCP), Council for International Organizations of Medical Sciences (CIOMS), World Health Organization (WHO) and SOPs]
 - Communications issued to and received from persons other than principal investigators, on matters that are not related to any study protocols
 - JEPeM-USM members and staff files (CVs, Appointment letters, Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE [JEPeM-USM FORM 1(C)]**, **TRAINING RECORDS [JEPeM-USM FORM 1(D)]**, Certificates of training
- 6.1.2 These documents are maintained separately from study protocol-related documents.
- 6.1.3 Reference materials and guidelines (the GCP, CIOMS, WHO and SOP) are kept in the reading corner of JEPeM-USM office and in the JEPeM-USM website.

6.2. Sorting and storage of documents

- 6.2.1. The Secretariat Staff labels and files administrative documents sequentially.
- 6.2.2. SOP Manuals are filed chronologically.
- 6.2.3. Important communications are filed in the communications folder and recorded

chronologically

- 6.2.4. Only the most recently updated **CURRICULUM VITAE [JEPeM-USM FORM 1(B)]** are filed in the individual member's folder.
- 6.2.5. Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURES [JEPeM-USM FORM 1(C)]** and training certificates are filed chronologically under every member's or staff's file.
- 6.2.6. **TRAINING RECORDS [JEPeM-USM FORM 1(D)]** must be updated as each training certificate is submitted by the member or staff for filing.
- 6.2.7. Active JEPeM-USM blank forms are downloaded from the website as necessary.

6.3. Disposal of unnecessary copies

- 6.3.1. Guidelines and references that have been superseded or outdated are removed from the files and disposed of properly.
- 6.3.2. Document files are shredded and disposed of for physical files. For electronic files, these will be permanently deleted from the system.

7. Active Study Files Workflow

ACTIVITY	RESPONSIBILITY
Create a coding system for active files ↓	Secretariat staff
Organize the contents of the active study files ↓	Secretariat Staff
Maintain the active study files	Secretariat Staff

DETAILED INSTRUCTIONS

7.1. Creation of coding system for active study files

- 7.1.1. Active files are study protocols that have been received by the JEPeM-USM Secretariat staff and are either undergoing review (full board or expedited review) or have been approved by the respective JEPeM-USM.
- 7.1.2. Active study files are coded as **USM/JEPeM/YYMM0000**, where YY represents the year, MM represents the month of receiving the first protocol, 0000 represents the sequential number.
- 7.1.3. The study file code should appear prominently on the study protocol folder.

7.1.4 Document timelines:

Description	Timelines (maximum)
Received completed protocol	Day 0
Secretariat compiles protocols for Chair/Panel Chair	5 working days
Panel Chair to assign Primary Reviewer(s)	5 working days
Secretariat to distribute the documents to the Primary Reviewers	3 working days
Primary reviewer (s) to complete review	10 working days
Secretariat to compile completed review protocols to be included for meeting (including protocol queue for next available meeting)	10 working days*
Secretariat to send out board decision letter (including list of correction) to PI	12 working days
Total	45 working days

*Pending availability of full board meeting

Note:

This is estimated timelines based on current protocol volume submitted.

7.2. Organization of contents of active study files

7.2.1. Study files are encoded into the Study Protocol Database, which contains the following information:

- JEPeM-USM Code
- Date Received
- Study Title
- Principal Investigator
- Co-investigators

7.2.2. The Secretariat Staff puts study protocol files in file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labeled with the title and code of the study protocol.

7.2.3. Folders are then kept in secure cabinets labeled as "Active Files". Soft copies of

relevant documents will be kept in secured Study Protocol Database.

7.2.4. Cabinets labeled as “Active Files” should only contain study file folders classified as “active.”

7.2.5. A study file folder contains the following documents, as applicable:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents (for clinical trials)
- Reviewers' assessment forms
- Committee's decisions in the form of excerpts from minutes
- Amendment reports
- Continuing review applications
- Final report
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Approval letters
- Action Letter/Notification of JEPeM-USM Decision
- Miscellaneous communication

7.3. Maintenance of active study protocol files

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

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

7.3.3. All Active File folders are maintained in the “Active Files” cabinet until the **FINAL REPORT FORM [JEPeM-USM FORM 3(C)]** is approved by the JEPeM-USM.

7.3.4. Completed protocol files will be appropriately marked/stamped and labelled as “COMPLETED”.

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

DETAILED INSTRUCTIONS

8.1. Management of Archived (inactive/completed/terminated) study files

- 8.1.1. Archived (Inactive/Completed/Terminated) study files are either:
- Study protocols with approved (by the JEPeM-USM) final reports, or
 - Study protocols declared *Inactive* by the secretariat if no replies are received from study team for a period of **forty (40) calendar days** following last communication or request from JEPeM-USM.
- 8.1.2. Upon receipt of **JEPeM-USM FORM 3(C): FINAL REPORT FORM**, the JEPeM-USM panel reviews it in accordance with **SOP III-4.3: FINAL REPORTS**.
- 8.1.3. Upon panel approval of the **JEPeM-USM FORM 3(C): FINAL REPORT FORM**, the Secretariat Staff removes the contents of the entire file from the active study filing area and verifies that all documents are present in an organized manner.
- 8.1.4. An archive number is assigned to the document by adding the year of archiving to the original code of the study file.
- 8.1.5. Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

8.2. Sorting of archived administrative documents

- 8.2.1. The Secretariat Staff should perform inventories of miscellaneous administrative documents yearly.
- 8.2.2. Unnecessary copies are disposed of accordingly (see **section 6.3** above).

8.3. Retrieval of documents

- 8.3.1. Only authorized JEPeM-USM Secretariat Staff can retrieve documents either from active study files or from the archives.
- 8.3.2. Active or inactive study files can be accessed, upon approval by the Chair. The files can only be viewed (eyes only) in the JEPeM-USM office.
- 8.3.3. An **ACCESS LOG [JEPeM-USM FORM 4(H)]** is placed in a pocket on the study file folder cover upon the first time it is accessed. (Non-borrowed files will not carry this pocket), and contains the following information:
- Study file code
 - Study Title
 - Date when access
 - By (person who requested access)
 - Signature of person who request access
 - Signature of Secretariat Staff upon return of document to file box.

- 8.3.4. PI can request for a copy of his/her protocol by writing to the Chair and justifying their request.

9. Maintaining confidentiality (of study files and JEPeM-USM documents) Workflow

ACTIVITY	RESPONSIBILITY
Classify documents as confidential ↓	JEPeM-USM
Request access to JEPeM-USM documents ↓	Members, non-members
Reproduce confidential documents ↓	Secretariat Staff
Maintain log of copies issued	Secretariat Staff

DETAILED INSTRUCTIONS

9.1. Classification of documents as confidential

- 9.1.1. Access to confidential documents is restricted by the JEPeM-USM to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.
- 9.1.2. The JEPeM-USM considers the following as confidential:
- Study protocols
 - Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
 - Meeting Minutes
 - Decisions, action letters/notification of JEPeM-USM decision, approval letters
 - Study protocol-related communications

9.2. Access to confidential JEPeM-USM documents

- 9.2.1. All JEPeM-USM members and the staff with a signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE [JEPeM-USM FORM 1(C)]** can have access to JEPeM-USM confidential documents upon request.
- 9.2.2. Non-members can access specific documents upon formal request and completion/signing of **CONFIDENTIALITY AGREEMENT FOR NON-MEMBERS [JEPeM-USM FORM 4(I)]**. The form requires the approval of the JEPeM-USM Chairperson/Deputy Chairperson. Regulatory authorities have full access to JEPeM-USM files provided it is within said authorities' mandate, and upon reasonable notice

to make the files available.

9.3. Reproduction of confidential documents

- 9.3.1. The Secretariat makes only the exact number of copies requested.
- 9.3.2 The recipient signs for the copies requested in the **JEPeM-USM FORM 4 (J): LOG OF REQUEST FOR COPIES OF DOCUMENTS** upon receipt of the copies.

9.4. Maintenance of log of copies

- 9.4.1 The Secretariat staff ensures the diligent recording of all document copies issued in the **JEPeM-USM FORM 4 (J): LOG OF REQUEST FOR COPIES OF DOCUMENTS**
- 9.4.2 This log is filed in a separate folder labeled Log of Copy Issued. Movement of all study files from the "File Room" needs to be recorded in the log book **JEPeM-USM FORM 4(P): LOG BOOK**