



## Standard Operating Procedures

### IV. DOCUMENTATION AND ARCHIVING

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### Document History

Author	Version	Date	Describe the main change
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 2016.
Prof. Dr. Hans Amin Van Rostenberghe, Prof. Dr. Nik Hazlina Nik Hussain and Mr. Mohd Bazlan Hafidz Mukrim.	04	10-05-2017	Fourth Version – Minor changes in the SOP. Also update the USM logo in all forms.
Prof. Dr. Hans Amin Van Rostenberghe, Dr. Soon Lean Keng and Mr. Mohd Bazlan Hafidz Mukrim.	05	07-01-2019	Fifth Version – Adding the page numbers to all the available forms.
Prof. Dr. Hans Amin Van Rostenberghe, Dr. Soon Lean Keng and Mr. Mohd Bazlan Hafidz Mukrim.	06	10-07-2019	Sixth Version – Minor technical changes in point no. 3, no. 4, no. 7, no. 8 and no.9.

Assoc. Prof. Dr. Wong Kah Keng, Assoc. Prof. Dr. Nor Hafizah Selamat, Dr. Husnaida Abdul Manan @ Sulong, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	07	30-08-2022	Seventh version – Minor technical changes in the SOP.
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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.

## 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.

#### 5.2. 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-USM/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
Assign Primary Reviewer(s)	5 working days
Completed review by Primary Reviewer(s)	10 working days
Protocol included for meeting	10 working days
Letter of communication to the PI after the meeting	15 working days
Approval letter after received correction	5 working days
<b>Total</b>	<b>45 working days</b>

**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.
- 9.4.3. Movement of all study files from the “File Room” needs to be recorded in the log book **JEPeM-USM FORM 4(P): LOG BOOK TEMPLATE**.
- 9.4.4. For the softcopy, it will be shared via institutional cloud storage.



**Minutes of  
<ordinal> REGULAR MEETING  
<dd/mm/yyyy>, Venue, Time**

## **1. ATTENDANCE**

### **PRESENT**

Member 1

Member 2

Member 3

Member 4

Member 5

Member 6

Member 7

Others:

Staff

## **2. CALL TO ORDER**

<Title, First Name, Surname>, **Chair**, called this regular meeting to order at <time> **AM**.

## **3. DETERMINATION OF QUORUM**

A quorum was declared with the presence of <number> members, inclusive of the presence of <number> non-institutional and <number> lay members, and as confirmed by the Secretary, <Title, Name, Surname>.

## **4. DISCLOSURE OF CONFLICT OF INTEREST**

<Title, Surname of Chair>, called for disclosure of Conflict of Interest (COI) in the Study Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the deliberations during the full board meeting for the following reasons:

<Title, Name, Surname> as **Principal Investigator** for the study entitled, "TITLE" (STUDY PROTOCOL NUMBER)

## **5. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**

<Title, Surname of Chair> presided over the discussion of the minutes of the (**JEPeM Review Panel**) meeting held last <dd/mm/yyyy> (**Date of last meeting**). The minutes were corrected during the discussion and approved as amended.

## MATTERS ARISING FROM THE MINUTES OF THE LAST MEETING

5.1. Corrections in the Minutes

5.2. Matters requiring JEPeM-USM action

## 6. STUDY PROTOCOL REVIEW

### 6.1. FULL REVIEW

#### 6.1.1. Resubmissions/Major Modifications of Study Protocols

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of interest	
Assessment of scientific soundness	<ol style="list-style-type: none"> <li>1. Objectives/Expected output</li> <li>2. Literature review</li> <li>3. Research design</li> <li>4. Sampling design, sample size</li> <li>5. Inclusion criteria, exclusion criteria, withdrawal criteria</li> <li>6. Specimen collection and processing</li> <li>7. Statistical and data analysis plan</li> <li>8. PI qualifications</li> <li>9. Suitability and choice of site</li> <li>10. Validation of research instruments among Malaysian participants</li> </ol>
Assessment of ethical issues	<ol style="list-style-type: none"> <li>1. Conflict of Interest:</li> <li>2. Privacy and confidentiality including data protection plan</li> <li>3. Vulnerability</li> <li>4. Risks</li> <li>5. Benefits</li> <li>6. Informed consent process and recruitment:</li> <li>7. Informed Consent Form (ICF) (including translation)</li> <li>8. Documentation of collaborative study TOR</li> </ol>
Conclusion and recommendations	
Action taken	Decision (Approval, Major Modification, Minor Modification, which requires re-evaluation by the primary reviewers, Minor Modification, which can be expedited at the level of the Chair, Resubmission, Disapproval)

#### 6.1.2. Study Protocols for Initial Review

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	



Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of interest	
Assessment of scientific soundness	<ol style="list-style-type: none"> <li>1. Objectives/Expected output</li> <li>2. Literature review</li> <li>3. Research design</li> <li>4. Sampling design, sample size</li> <li>5. Inclusion criteria, exclusion criteria, withdrawal criteria</li> <li>6. Specimen collection and processing</li> <li>7. Statistical and data analysis plan</li> <li>8. PI qualifications</li> <li>9. Suitability and choice of site</li> <li>10. Validation of research instruments among Malaysian participants</li> </ol>
Assessment of ethical issues	<ol style="list-style-type: none"> <li>1. Conflict of Interest:</li> <li>2. Privacy and confidentiality including data protection plan</li> <li>3. Vulnerability</li> <li>4. Risks</li> <li>5. Benefits</li> <li>6. Informed consent process and recruitment:</li> <li>7. Informed Consent Form (ICF) (including translation)</li> <li>8. Documentation of collaborative study TOR</li> </ol>
Conclusion and recommendations	
Action taken	<b>Decision</b> (Approval, Major Modification, Minor Modification, which requires re-evaluation by the primary reviewers, Minor Modification, which can be expedited at the level of the Chair, Resubmission, Disapproval)

#### 6.1.3. Study Protocol Amendment Applications:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of amendment requested</b>	
Conclusion and recommendations	
Action taken	<b>Decision</b> (Approval, Minor modification to the proposed amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the proposed amendment, stating reasons for action, subject to

	full board review, Disapproval)
Reasons	

#### 6.1.4. Continuing Review Applications:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of progress reported</b>	
Conclusion and recommendations	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action)
Reasons	

#### 6.1.5. Final Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of final report</b>	
Conclusion and recommendations	
Action taken	<b>Decision Points</b> (Approve, Request information, Recommend further action)
Reasons	

#### 6.1.6. SAE and SUSAR Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	

Primary Reviewers		
Technical Review		
Sponsor		
Quorum status		
Conflict of Interest:		
<b>Assessment of SAEs reported</b>		
SAE 1	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	<dd/mm/yyyy>
	Age	
	Sex	
	Country	
	Nature of AE	
	Co-morbidities	
Status		
Conclusion and recommendations		
Action taken	<b>Decision Points</b> (Uphold original approval with no further action, Request information, Recommend further action)	
Reasons		
SAE 2	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	<dd/mm/yyyy>
	Age	
	Sex	
	Country	
	Nature of SAE	
	Co-morbidities	
Status		
Conclusion and recommendations		
Action taken	<b>Decision Points</b> (Uphold original approval with no further action, Request information, Recommend further action)	
Reasons		

#### 6.1.7. Site Visit Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	

<b>Assessment of Site Visit Report</b>	
Conclusion and recommendations	
Action taken	<b>Decision Points</b> (Uphold original approval with no further action, Request information, Recommend further action)
Reasons	

**6.1.8. Study Protocol Non-Compliance (Deviation or Violation) Reports:**

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of Non-Compliance Report</b>	
Conclusion and recommendations	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action, Forward to SAE Subcommittee)
Reasons	

**6.1.9. Early Study Termination Applications**

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of risks from early termination</b>	
Conclusion and recommendations	
Action taken	<b>Decision</b> (Approval, Request information, Recommend further action)
Reasons	

**6.1.10. Queries or Complaints**

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>

Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
<b>Assessment of query or complaint</b>	
Conclusion and recommendations	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action)
Reasons	

## 6.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR

### 6.2.1. Study Protocols for Initial Review

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapproval)

### 6.2.2. Study Protocol Amendments

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Amendment Submission	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Approval, Minor modification to the proposed amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the proposed amendment, stating reasons for action, subject to full board review, Disapproval)

### 6.2.3. Continuing Review Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action)

### 6.2.4. Final Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision Points</b> (Approval, Recommend further action)

### 6.2.5. Study Protocol Non-Compliance (Deviation or Violation) Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action, Forward to AE Subcommittee)

### 6.2.6. Early Study Termination Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Approval, Request information, Recommend further action)

**6.2.7. Queries or Complaints**

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	<b>Decision</b> (Uphold original approval with no further action, Request information, Recommend further action)

**7. OTHER MATTERS**

**8. ADJOURNMENT**

Meeting was adjourned at **<time>**

Prepared by:	Signature over <Title, Name, Surname>
DATE: <dd/mm/yyyy>	SECRETARY/SECRETARIAT STAFF
Checked by:	Signature over <Title, Name, Surname>
DATE: <dd/mm/yyyy>	MEMBER SECRETARY
Approved by:	Signature over <Title, Name, Surname>
DATE: <dd/mm/yyyy>	CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR

<JEPeM Official Letterhead>

<dd/mm/yyyy>

<TITLE, NAME, SURNAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

JEPeM Code :

Protocol Title :

Dear <TITLE OF PI>

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code <JEPeM-USM code>, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **<date of approval> until <expiration date>**.

Study Site:

The following researchers also involve in this study:

- 1.
- 2.
- 3.

The following documents have been approved for use in the study.

1. Study Protocol <version #>

In addition to the abovementioned documents, the following technical document/s was/were included in the review on which this approval was based:

1. Study Protocol file 3 <version #>
2. Study Protocol file 4 <version #>

Attached document: List of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review**



- Application Form.** Subsequently this needs to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
  3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
  4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
  5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019: Early Study Termination Application Form.**
  6. Any event which may have ethical significance.
  7. Any information which is needed by the JEPeM-USM to do ongoing review.
  8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: [www.jepem.kk.usm.my](http://www.jepem.kk.usm.my)

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Very truly yours,

<NAME OF CHAIRPERSON/DEPUTY CHAIRPERSON>

Chairperson/Deputy Chairperson, JEPeM-USM

<dd/mm/yyyy>

<NAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

JEPeM-USM Code :

Protocol Title :

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) reviewed your proposed ethical application during its regular meeting <date of meeting> and is requesting further clarification. Your study has been assigned study protocol code <JEPeM-USM code>, which should be used for all communication to the JEPeM-USM related to this study.

As a result of the review, the decision of the committee is **MAJOR MODIFICATIONS PRIOR TO APPROVAL/MINOR MODIFICATIONS PRIOR TO APPROVAL/RESUBMISSION**. Recommended revisions and/or clarifications are summarized in the 'conclusion and recommendations' part in the provided attachment.

Please note that revisions requested by the JEPeM-USM should:

1. Be integrated into a revised STUDY PROTOCOL/PACKAGE and related documents in one printed copy.
2. Be SUMMARIZED in a cover letter indicating in which page of the revised study protocol the respective revision may be found;
3. Modified part should be underlined and **bold**; and

The cut-off date for submission of revised study protocol is on <Date> which is 40 calendar days from the date of this letter. Failure to respond before or on <Date> will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the JEPeM-USM Secretariat at 09 7672354 or jepem@usm.my

The JEPeM-USM looks forward to your immediate response and action.

Very truly yours,

Secretary

On behalf of Chairperson

Jawatankuasa Etika Penyelidikan (Manusia) USM

< dd/mm/yyyy>

**<NAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

**< JEPeM-USM Code>**

**<Study Protocol Title>**

Dear **<TITLE OF PI> <SURNAME>**:

Following your application submitted on <date of submission>, the Jawatankuasa Etika Penyelidikan (Manusia) USM would like to invite you to attend the next full board meeting to clarify some issues with regards to your application. Your appointment is as below:

Date : <Date>

Time : <Time>

Mode : Face to face / Online 'WEBEX' application

The secretariat will email the WEBEX link of the meeting to you soon.

There are a few requirements when you attend the interview. These are as follows:

- A. For student applicant, whether undergraduate or postgraduate, it is compulsory for the supervisor to be present during the session.
- B. You are required to present a 3-minute oral summary of your proposal. This may include a short introduction to the subject area, study justification, objectives, methodology, etc. We discourage Powerpoint slides presentation.

Please don't be hesitant to contact me if you have any enquiries or require assistance. We look forward to your immediate response and action.

Very truly yours,

**<NAME OF SECRETARY>**

Secretary, JEPeM-USM

<dd/mm/yyyy>

<NAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> <Study Protocol Code>**

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) has approved the proposed amendment/s in your study entitled, "**Study Protocol Title**" (**JEPeM-USM Code**) during its meeting on <Date of Full Board meeting>. Upon reviewing of JEPeM-USM FORM 3(A): Study Protocol Amendment Submission Form and <proposed amendment/s>, the following documents have been approved for use:

1. Study Protocol <version #> <date of document>
2. Please submit to the JEPeM-USM secretariat the final version of protocol or protocol related document(s) that was/were amended.

Thank you.

Very truly yours,

<NAME OF CHAIRPERSON/DEPUTY CHAIRPERSON>

Chair, JEPeM-USM

<dd/mm/yyyy>

**<NAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> <Study Protocol Code>**

Dear **<TITLE OF PI> <SURNAME>**:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) acknowledged receipt of *<Continuing Review Application/Final Report/Study Protocol Non-Compliance Record/SAE Report/Site Visit Report>* dated *<date of document>*.

Upon review of *<JEPeM-USM FORM 3(B):Continuing Review Application Form/ JEPeM-USM FORM 3(C):Final Report Form/ JEPeM-USM FORM 3(D):Study Protocol Non-Compliance Record/ JEPeM-USM FORM 3(G): Serious Adverse Event Report Form/ JEPeM-USM FORM 3(F): Site Visit Report Form >* and *<submitted document/s>*, The committee's decision is **< REQUEST INFORMATION/RECOMMENDATION FOR FURTHER ACTION/FORWARD TO SAE SUBCOMMITTEE>**. Recommended revisions and/or clarifications are summarized below:

1.

Please note that modification/revision/resubmissions can only be accepted within 40 calendar days from the date of this letter. Failure to respond on or before *<Date>* will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the JEPeM-USM Secretariat at 09 7672354 or jepem@usm.my

The JEPeM-USM looks forward to your immediate response and action.

Very truly yours,

Secretary  
On behalf of Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia) USM

< dd/mm/yyyy>

<NAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> <Study Protocol Code>**

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM reviewed the <withdrawal of study protocol application/final report/early study termination application> for your study entitled, "**Study Protocol Title**" (JEPeM-USM Code) during its meeting on <Date of Full Board meeting>.

Upon review of <JEPeM-USM Form 3(C): Final Report Form/JEPeM-USM Form 3(E): Early Study Termination Application Form> and <submitted document/s>, the committee **APPROVED** the <withdrawal if study protocol application/final report/early study termination application> and recommended the commencement of archiving procedures. The protocol is reclassified as **INACTIVE** and ethical clearance automatically **EXPIRED** effective <Date of Full Board meeting>. The protocol records will be made available for **three years** from this date.

Thank you.

Very truly yours,

<NAME OF CHAIRPERSON>

Chair, JEPeM-USM



<b>JEPeM Code: USM/JEPeM/</b>				
<b>Borrower's Name</b>	<b>Signature</b>	<b>Date Borrowed</b>	<b>Received by</b>	<b>Date Received</b>

**Confidentiality Agreement for Non-members**

I, \_\_\_\_\_ as a non-member of the JEPeM-USM, understand that the copy (ies) given to me by the JEPeM-USM are confidential. I shall use the information only for the indicated purpose as described to the JEPeM-USM and shall not duplicate, give or distribute these documents to any person(s) without permission from the JEPeM-USM. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following JEPeM-USM documents:

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<b>RECIPIENT</b>	Signature	
Date:	Name	_____
		_____

<b>SECRETARY</b>	Signature	
Date:	Name	_____
<b>JEPeM-USM CHAIR</b>	Signature	
Date:	Name	_____





**Log of Request for Copies of Documents**

Title of Document	Name of Recipient	# of Copies	Reasons for the Request	Signature of Recipient	Initials of Secretariat Staff	Date Out	Date In

*Note: This log should be attached to the original documents.*

Date of meeting :  
 Venue :  
 Time :  
 Meeting No :

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
<b>Chairperson/Deputy Chairperson:</b>	Chairperson/Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM		✓ <b>(Chairperson/ Deputy Chairperson)</b>
<b>Secretary:</b>			✓
<b>Members :</b>			
1.			✓
2.			✓
3.			✓
4.			✓
5.			✓
6.			✓
7.			✓
8.			✓
9.			✓
10.			✓

**Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.**

**(TITLE & NAME)**

Chairperson/Deputy Chairperson  
 Jawatankuasa Etika Penyelidikan (Manusia), JEPeM  
 Universiti Sains Malaysia

<dd/mm/yyyy>

**<NAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> < JEPeM-USM CODE>**

Dear **<TITLE OF PI> <SURNAME>**:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) acknowledges the receipt of *<Continuing Review Application/ Study Protocol Deviation Record/SAE Report/Site Visit Report>* dated *<date of document>*.

Upon reviewing of *<JEPeM-USM FORM 3(B): Continuing Review Application Form/JEPeM-USM FORM 3(D): Study Protocol Deviation Record/ JEPeM-USM FORM 3(G): Adverse Event Report Form/ JEPeM-USM FORM 3(F): Site Visit Report Form >* and *<submitted document/s>*, the committee's decision is:

**EXTENSION OF APPROVAL UNTIL (DATE) /MAINTAIN ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUIRED.**

Thank you for your continuing compliance with the requirements of the JEPeM-USM.

Very truly yours,

**<NAME OF CHAIRPERSON>**

Chair, JEPeM-USM

**Submissions Log**

DATE RECEIVED	JEPeM-USM CODE	TITLE	PRINCIPAL INVESTIGATOR	SENT BY	RECEIVED BY	DATE OF DOCUMENT	TYPE OF SUBMISSION	CONTENT OF SUBMISSION	MODE OF DELIVERY	STAFF ACTION	FURTHER ACTION REQUIRED
			Name	Name	Name						

<dd/mm/yyyy>

**<TITLE, NAME, SURNAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> <JEPeM-USM Code>**

Dear **<TITLE OF PI> <SURNAME>**:

We wish to remind you that the <progress/final> report for the study protocol **<Study Protocol Title> <JEPeM-USM Code>** is due on/had been due since < every six months from date of approval >. Based on the records of the **Jawatankuasa Etika Penyelidikan (Manusia) (JEPeM-USM) <Review Panel>**, there had been no communication regarding the progress of this study, which is still in our active file and has an active ethical clearance. If the study had been concluded or terminated, kindly fill out a final report form **[JEPeM-USM FORM 3(C)]**; or if still ongoing, a continuing review form **[JEPeM-USM FORM 3(B)]**. The forms are attached herein.

Kindly submit the relevant report/form within thirty (30) calendar days of receiving this letter. If no submission is received within the indicated grace period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the **JEPeM-USM** Secretariat at 09-7672354/09-7672362 or jepem@usm.my.

The **JEPeM-USM** looks forward to your immediate response and action.

Thank you.

Very truly yours,

**<NAME OF SECRETARY>**

Secretary, **JEPeM-USM**

<dd/mm/yyyy>

**<TITLE, NAME, SURNAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

**Re: <Study Protocol Title> <JEPeM-USM Code>**

Dear **<TITLE OF PI> <SURNAME>**:

We wish to remind you that the <revised study protocol submission> for the protocol entitled **<Study Protocol Title> <JEPeM-USM Code>** is due on <cut-off date >. Based on the records of the **Jawatankuasa Etika Penyelidikan (Manusia) (JEPeM-USM)**, there had been no communication regarding the revised study protocol submission of this study since the meeting held on <date of the meeting>.

Kindly submit the relevant documents before or on <cut-off date >. If no submission is received within the date, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the **JEPeM-USM** Secretariat at 09-7672354/09-7672362 or jepem@usm.my.

The **JEPeM-USM** looks forward to your immediate response and action.

Thank you.

Very truly yours,

**<NAME OF SECRETARY>**

Secretary, **JEPeM-USM**

**Log Book Template (Records of File Movement)**

No.	Date (Out)	Date (In)	Reasons for the Request	File: JEPeM-USM Code	Signature of Secretariat Staff	Date of Signature