Standard Operating Procedures
III. POST-APPROVAL REVIEW

1. Objectives
2. Scope
3. Responsibilities
4. Work Flow
5. SAE and SUSAR
6. Site Visit

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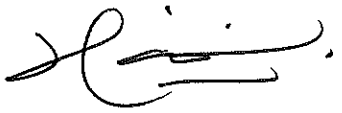
Approved by:	 Professor Dato' Dr. Faisal Rafiq Mahamd Adikan Vice Chancellor, Universiti Sains Malaysia
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Document History

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. Hans Amin Van Rostenberghe, Assoc. Prof. Oleksandr Krasilshchikov, Assoc. Prof. Dr. Noraida Ramli, Dr. Azlan Husin, Mr. Harry Mulder and Miss Siti Fatihah Ariffin	02	07/09/2015	Second version – minor changes in the form 3(A), 3(B) and 3(C).
Prof. Dr. Hans Amin Van Rostenberghe, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatihah Ariffin	03	10/08/2016	Third version – minor changes in the form 3(A), 3(B), 3(C), 3(D), 3(E), 3(F), 3(G) and 3(I) based on the recommendation made during inspection by BPFK on 12-14 April 2016.
Prof. Dr. Hans Amin Van Rostenberghe, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatihah Ariffin	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, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatihah Ariffin	05	07/01/2019	Fifth Version – Minor technical changes in point no. 4. Also adding the page numbers to all the available forms.
Prof. Dr. Hans Amin Van Rostenberghe, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatihah Ariffin	06	10/07/2019	Sixth Version – Minor technical changes in point no. 4, no. 5 and no.6.

Assoc. Prof. Dr. Azlan Husin, Dr. Noor Aman A. Hamid, Mr. Mohd Bazlan Hafidz Mukrim and Mr. Mohammad Haris Amirul Mohd Yusoff	07	30/08/2022	Seventh Version – minor changes in overall of the SOP III.

1. Objectives

This SOP describes how the JEPeM-USM processes post approval submissions by the Principal Investigators. Depending on the nature of the submissions, they may be processed by either "expedited" or full board review. This chapter describes submission procedures, required forms, documentation of board action, communication of board action to the PI, and filing of results.

2. Scope

This SOP applies to all study protocol-related submissions after approval has been issued for the study protocol and study protocol-related documents. These submissions include requests for amendments, continuing review applications, final reports, non-compliance (deviation or violation) reports, early study termination, queries or complaints from stakeholders, serious adverse event reports (SAEs) and suspected unexpected serious drug reactions (SUSARs), and site visit reports.

3. Responsibilities

It is the responsibility of the PI to comply with post-approval review requirements, including the submission of required reports listed in **JEPeM-USM FORM 4(B): APPROVAL LETTER TO THE STUDY PROTOCOL.**

The Secretariat Staff is responsible for receiving and processing all submissions, including inquiries or complaints from research participants and other stakeholders. JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary will decide on type of review for post approval application into full board or expedited review. For full board decision, the primary reviewer(s) is/are requested to review relevant documents related to this.

In the event that a Site Visit becomes necessary as decided by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary, it is the responsibility of the Chairperson of Site Visit Sub-Committee Team to form a Site Visit Team. The responsibility of the assigned members to conduct the Site Visit and issue a report for presentation in the JEPeM-USM full board meeting, and responsibility of the Secretariat Staff to organize the Site Visit.

4. Study Protocol Amendments, Continuing Review Applications, Final Reports, Noncompliance Reports, Early Study Termination Application, and Participant Queries or Complaints Workflow

ACTIVITY	RESPONSIBILITY
Receive and manage documents submission ↓	Secretariat Staff
Submit documents to the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary to determine classification of review as expedited or full board ↓	Secretariat Staff
JEPeM-USM Chairperson/ Deputy Chairperson/Panel Chair/Member Secretary reviews submissions classified as expedited review; Primary reviewers review submissions classified as full board review	JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary/Primary Reviewers
Review full board study protocols in JEPeM-USM meeting ↓	Members
Communicate results to PI/Participant ↓	Secretariat Staff
Manage study protocol files	Secretariat Staff

DETAILED INSTRUCTIONS

4.1. Study Protocol Amendment

4.1.1. *Receipt and management of the Study Protocol Amendment package upon submission*

4.1.1.1. A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the JEPeM-USM that issued the ethical clearance or approval prior to the implementation of an amendment.

4.1.1.2. A study protocol amendment is facilitated through the submission of **JEPeM-USM FORM 3(A): STUDY PROTOCOL AMENDMENT SUBMISSION FORM** with the amended study protocol or protocol- related documents by the principal investigator to the JEPeM-USM that issued the ethical clearance or approval to the study protocol. This comprises the study protocol amendment package.

4.1.1.3. Upon receipt of the study protocol amendment package, the Secretariat Staff logs the date of submission on the database.

4.1.1.4. The Secretariat Staff checks the submission for completeness and gives an acknowledgement of receipt of **FORM JEPeM-USM FORM 3(A): STUDY**

PROTOCOL AMENDMENT SUBMISSION to the PI or representative. If incomplete submission, the secretariat staff will request PI or representative to complete the submission.

4.1.1.5. The Secretariat Staff ensures that sufficient copies (5 hardcopy/1 softcopy) relevant document related to protocol amendment including documents with track changes and clean version for the JEPeM-USM Members have been submitted by the PI or representative for submissions.

4.1.2. *Classification of Review by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary*

4.1.2.1. The Secretariat Staff sends the Study Protocol Submission Package to the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary immediately for classification of review as expedited or full board.

4.1.2.2. A full board review is necessary if the proposed study protocol amendment increases risk to study participants, as assessed by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary, such as a change in study design, which may include but is not limited to:

- Additional treatments or the deletion of treatments
- Any changes in inclusion/exclusion criteria
- Change in method of dosage formulation, (e.g. oral changed to intravenous)
- Significant change in the number of subjects
- Significant decrease or increase in dosage amounts

4.1.3. *Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary and Primary Reviewers*

4.1.3.1. For submissions under expedited review, action is taken at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days.** The decision will be endorsed in the next full board meeting.

4.1.3.2. Study protocol amendment packages subject to full board review will be forwarded to the primary reviewers who will complete the review within **ten (10) working days**. In the event where primary reviewers are no longer available, new reviewers will be appointed by Chairperson/Deputy Chairperson/Panel Chair/Member Secretary.

4.1.3.3. The Primary Reviewers accomplish the review and return the signed **JEPeM-USM FORM 3(A): STUDY PROTOCOL AMENDMENT SUBMISSION**

FORM to JEPeM-USM together with the Study Protocol Amendment Package.

4.1.3.4. The Secretariat Staff places the study protocol amendment request on the agenda for the next JEPeM-USM meeting.

4.1.4. *Full board review of Study Protocol Amendment Submission Package*

4.1.4.1. The Secretariat Staff distributes the following Study Protocol Amendment Package to JEPeM-USM Members along with the meeting agenda:

- **JEPeM-USM FORM 3(A): STUDY PROTOCOL AMENDMENT SUBMISSION FORM**
- Amended study protocol or protocol-related document; with amended section clearly indicated
- Other documents that have been affected by the revision

4.1.4.2. The documents are presented to JEPeM-USM Members when amendments are deliberated on. For detailed information on the conduct of full board review of study protocol amendments, see **SOP II-8.8.1.**

4.1.5. *Communication of Results*

4.1.5.1. The PI is notified of the JEPeM-USM decision noting which amended documents are approved for use through an action letter.

4.1.5.2. The PI may be required to modify the amendment, provide additional information, or submit additional documents.

4.1.5.3. If the amendment is approved, the PI is requested to submit an amended study protocol or protocol-related document with a new version number and date.

4.1.6. *Files Management*

4.1.6.1. The Secretariat Staff receives the approved amended study protocol or protocol- related document with a new version number and date and stamps it “APPROVED” with the approval date. For electronic version, it will be stamped electronically.

4.1.6.2. The newly approved documents will supersede previous versions of the study protocol or protocol-related document.

4.1.6.3. The Secretariat Staff files the signed and approved documents in the study protocol folder.

4.2. Continuing Review Application

4.2.1. *Receipt and management of the Continuing Review Application package upon submission*

4.2.1.1. Ethical clearance or approval is typically granted for a period of one year. After approval, continuing review is required to be done at least once a year, depending on the risk assessment of the study protocol. This is facilitated through the submission of **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION FORM**.

4.2.1.2. The frequency of continuing review is indicated in **JEPeM-USM FORM 4(B): APPROVAL LETTER TO THE STUDY PROTOCOL,** which is provided to the PI upon approval of the study.

4.2.1.3. For ethical clearance or approval approaching one year expiry date and requiring a renewal or extension, it is advisable to submit **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION FORM 60 calendar days** prior to expiry date.

4.2.1.4. The Secretariat Staff informs the respective PIs at least **90 calendar days** before expiry date of the approval by fax, e-mail, or post using **JEPeM-USM FORM 4(N): REMINDER LETTER FOR CONTINUING REVIEW OR FINAL REPORT** and keeps a copy of the communication.

4.2.1.5. The continuing review application is facilitated through the submission of **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION FORM.**

4.2.1.6. The Secretariat Staff checks the submission for completeness and gives acknowledgment of **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION FORM** to the PI or representative.

4.2.1.7. The Secretariat Staff logs the date of submission on the database.

4.2.1.8. The Secretariat Staff ensures that sufficient copies (5 hardcopy/1 softcopy) relevant document related to continuing review for the JEPeM-USM Members have been submitted by the PI or representative for submissions.

4.2.2. Classification of Review by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary

4.2.2.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary classifies the submission as either full board or expedited review.

4.2.2.2. Generally, classification of continuing review as expedited or full board is based on the initial review classification (i.e. continuing review of full board study protocols is done through full board review); unless otherwise indicated by the specificities of the submitted information. If the approval has expired for more than 1 year, the PI will be invited to full board meeting for further clarification.

4.2.3. *Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary and Primary Reviewers*

4.2.3.1. The continuing review application package is sent together with a copy of the study protocol to the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary for expedited review study protocols. For full board review study protocols, the review of the application is done by the the primary reviewers. In the event where primary reviewers are no longer available, new reviewers will be appointed by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary.

4.2.3.2. For submissions under expedited review, action is finalized at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days**.

4.2.3.3. For submission under full board review, JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary /Primary Reviewers accomplish the review and return the signed **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION SUBMISSION FORM** to JEPeM-USM together with relevant documents.

4.2.3.4. The Secretariat Staff places the continuing review application on the agenda for the next JEPeM-USM meeting.

4.2.4. *Full Board Review of Continuing Review Application*

4.2.4.1. The Secretariat Staff distributes the following continuing review application package to JEPeM-USM Members along with the meeting agenda:

- **JEPeM-USM FORM 3(B): CONTINUING REVIEW APPLICATION FORM**
- **Study protocol synopsis**

- Current informed consent documents

4.2.4.2. The documents are presented to JEPeM-USM Members when continuing review applications are deliberated on. For detailed information on the conduct of full board review of continuing review applications, see **SOP II-8.8.2.**

4.2.5. *Communication of Results*

4.2.5.1. The PI is notified of the decision noting board action on the continuing review application through a letter.

4.2.5.2. The PI may be requested to provide additional information or submit additional documents.

4.2.6. *Files Management*

4.2.6.1. The Secretariat Staff files the signed continuing review application documents in the study protocol file folder. For electronic version, it will be stamped electronically.

4.3. Final Report

4.3.1. *Management of the Final Report Package upon Submission*

4.3.1.1. Upon completion of the study, the investigator should provide the JEPEM-USM with a summary of the outcome of the study, especially of the human participants who were involved using **JEPeM-USM FORM 3(C[i] or C[ii]): FINAL REPORT FORM**.

4.3.1.2. The Secretariat Staff will remind the respective PIs 90 days before the study protocol is expired to submit a Final Report at least one month in advance of the due date of review by fax, e-mail, or post using **JEPeM-USM FORM 4(N): REMINDER LETTER FOR CONTINUING REVIEW OR FINAL REPORT** and keeps a copy of the communication.

4.3.1.3. The end of study reporting is facilitated through the submission of **JEPeM-USM FORM 3(C[i] or C[ii]): FINAL REPORT FORM,** together with documents deemed relevant by the investigator to clarify information indicated in the final report. This comprises the final report package. For clinical trials form C[i] will be used and for other studies form C[ii].

4.3.1.4. The Secretariat Staff checks the submission for completeness and gives an acknowledgment of receipt of **JEPeM-USM FORM 3(C[i] or C[ii]): FINAL REPORT FORM** to the PI or representative. If incomplete submission, the

secretariat staff will request PI or representative to complete the submission

4.3.1.5. The Secretariat Staff logs the date of submission on the database.

4.3.2. ***Classification of Review by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary***

4.3.2.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary classifies the submission as either full board or expedited review.

4.3.2.2. Generally, classification as expedited or full board is based on the initial review classification (i.e. final report review of full board study protocols is done through full board review); unless otherwise indicated by the specificities of the submitted information.

4.3.3. ***Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary and Primary Reviewers***

4.3.3.1. The final report package is sent together with a copy of the study protocol to the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary/Primary Reviewers. For full board review study protocols, the review of the final report package is done by the the primary reviewers. In the event where primary reviewers are no longer available, new reviewers will be appointed by JEPeM-USM chairperson/deputy chairperson/panel chair/member secretary.

4.3.3.2. For submissions under expedited review, action is finalized at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days**.

4.3.3.3. For submission under full board review, the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary /Primary Reviewers accomplish the review and return the signed **JEPeM-USM FORM 3(C[i] or C[ii]) : FINAL REPORT FORM.**

4.3.3.4. The Secretariat Staff places the final report package on the agenda for the next JEPeM-USM meeting.

4.3.4. ***Full Board Review of Final Report***

4.3.4.1. The Secretariat Staff distributes the following final report package to JEPeM-USM Members along with the meeting agenda:

- **JEPeM-USM FORM 3(C[i] or C[ii]): FINAL REPORT FORM**

- Relevant documents

4.3.4.2. The documents are presented to JEPeM-USM Members when final reports are deliberated on. For detailed information on the conduct of full board review of final reports, see **SOP II-8.8.3.**

4.3.5. *Communication of Results*

4.3.5.1. The PI is notified of the JEPeM-USM decision, noting JEPeM-USM action on the final report through a letter.

4.3.5.2. The PI may be requested to provide additional information or submit additional documents, in which case the final report may be accepted, but action regarding archiving may be deferred pending submission of results of the study.

4.3.5.3. If the final report is approved, the PI is informed of the following:

- The protocol is classified as inactive
- Study protocol records will be made available for **three (3) years** in the archives after the expiration date.

4.3.5.4 PI or his/her representative will be notified after 6 months after the expiry date and the second reminder will be made and copied to HOD/PTJ. If there is no submission from the PI or representative, JEPeM-USM will classify the protocol as INACTIVE.

4.3.6. *Files Management*

4.3.6.1. The Secretariat Staff files the signed final report documents in the study protocol file folder, upon approval of the final report, when no further action is expected from the PI. For electronic version, it will be stamped electronically.

4.3.6.2. The Secretariat Staff enters relevant study protocol data into the Study Protocol Database to signify the end of study.

4.3.6.3. The Secretariat Staff transfers the study protocol folder to the inactive files. See **SOP IV-8: Archived (Inactive/Completed/Terminated) Files** for management of inactive files.

4.4. Study Protocol Noncompliance (Deviation/Violation) Report

4.4.1. *Management of the Study Protocol Noncompliance Reports upon Submission*

4.4.1.1. The investigator should document, explain, and report to the JEPeM-USM any noncompliance from the approved protocol, whether minor or major, at the soonest possible time.

4.4.1.2. The investigator may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior JEPeM-USM approval, but must submit as soon as possible, a report of deviation or change, the reasons for it, and, if appropriate, an appropriate study protocol amendment(s).

4.4.1.3. Reporting of study protocol noncompliance is facilitated through the submission of **JEPeM-USM FORM 3(D): STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT,** together with documents deemed relevant by the investigator to clarify information indicated in the report. This comprises the study protocol noncompliance report package.

4.4.1.4. The Secretariat Staff checks the submission for completeness and gives an acknowledgment of receipt of **JEPeM-USM FORM 3(D): STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT** to the PI or representative. If incomplete submission, the secretariat staff will request PI or representative to complete the submission.

4.4.1.5. The Secretariat Staff logs the date of submission on the database.

4.4.2. *Classification of Review by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary*

4.4.2.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary classifies the submission as either full board or expedited review.

4.4.2.2. Minor or administrative deviations which do not affect the scientific soundness of the study protocol or compromise the rights, safety, or welfare of human participants in the study are classified under expedited review.

4.4.2.3. Major deviations or protocol violations that consist of persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk are classified under full board review.

4.4.3. *Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary/Primary Reviewer*

4.4.3.1. For submissions under expedited review, action is finalized at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days**.

4.4.3.2. Submissions subject to full board review will be forwarded to the primary reviewers who will complete the review within **ten (10) working days**. In the event where primary reviewers are no longer available, new reviewers will be appointed by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary.

4.4.3.3. The Primary Reviewers accomplishes the review and returns the signed **JEPeM-USM FORM 3(D): STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT.**

4.4.3.4. The Secretariat Staff places the study protocol noncompliance report on the agenda for the next JEPeM-USM meeting.

4.4.4. *Full Board Review of Study Protocol Noncompliance Report*

4.4.4.1. The Secretariat Staff distributes the following Study Protocol Noncompliance Report Package to JEPeM-USM Members along with the meeting agenda:

- **JEPeM-USM FORM 3(D): STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT**
- Documents related to the deviation

4.4.4.2. The documents are presented to JEPeM-USM members when study protocol noncompliance reports are deliberated on. The JEPeM-USM deliberates on both the type and degree of noncompliance and takes the appropriate action.

4.4.4.3. The JEPeM-USM can suspend ethical clearance or subject recruitment until noncompliance issues are addressed.

4.4.4.4. The JEPeM-USM may opt to withdraw ethical approval under the following circumstances:

- Fraud
- Unresolved serious safety issues

4.4.4.5. For detailed information on full board review of study protocol noncompliance report, **see SOP II-8.8.6**.

4.4.5. *Communication of Results*

4.4.5.1. The PI is notified of the JEPeM-USM decision, noting JEPeM-USM action on the study protocol noncompliance report through a letter.

4.4.5.2. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

4.4.6. *Files Management*

4.4.6.1. The Secretariat Staff files the signed study protocol noncompliance report documents in the study protocol file folder. For electronic version, it will be stamped electronically.

4.5. Early Study Termination Application

4.5.1. *Management of the Early Study Termination Application upon Submission*

4.5.1.1. An application for early study termination is submitted when a study approved by the JEPEM-USM is being recommended for termination before its scheduled completion. This is done when the safety of the study participant is doubtful or at risk and also upon the request of the PI or the sponsor owing to the existence of irresolvable valid complaints.

4.5.1.2. Early study termination is facilitated through the submission of **JEPeM-USM FORM 3(E): EARLY STUDY TERMINATION APPLICATION FORM,** together with documents deemed relevant by the investigator to support or clarify information indicated in the application. This comprises the early study termination application package.

4.5.1.3. The Secretariat Staff checks the submission for completeness and gives an acknowledgement of receipt of **JEPeM-USM FORM 3(E): EARLY STUDY TERMINATION APPLICATION FORM** to the PI or representative. If incomplete submission, the secretariat staff will request PI or representative to complete the submission.

4.5.1.4. The Secretariat Staff logs the date of submission on the database.

4.5.2. *Classification of Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary*

4.5.2.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary classifies the submission as either full board or expedited review.

4.5.2.2. Generally, classification of review of early study termination applications as expedited or full board is based on the initial review classification (i.e. early study termination application of full board study protocols is done through full board review); unless otherwise indicated by the specificities of the submitted information.

4.5.3. *Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary and Primary Reviewers*

4.5.3.1. For submissions under expedited review, action is finalized at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days**.

4.5.3.2. Submissions subject to full board review will be forwarded to the primary reviewers who will complete the review within **ten (10) working days.** In the event where primary reviewers are no longer available, new reviewers will be appointed by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary.

4.5.3.3. The Primary Reviewer accomplishes the review and returns the signed **JEPeM-USM FORM 3(E): EARLY STUDY TERMINATION APPLICATION FORM.**

4.5.3.4. The Secretariat Staff places the early study termination application on the agenda for the next JEPeM-USM meeting or if there are urgent issues, a special meeting can be called by the JEPeM-USM chairperson.

4.5.4. *Full Board Review of Early Study Termination Application*

4.5.4.1. The Secretariat Staff distributes the following early study termination application package to JEPeM-USM Members along with the meeting agenda:

- **JEPeM-USM FORM 3(E): EARLY STUDY TERMINATION APPLICATION FORM**
- Documents related to the early study termination

4.5.4.2. The JEPeM-USM deliberates on the implications of the application on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants.

4.5.4.3. The JEPeM-USM may request information for clarification by email or interview from the PI or representative

1.1.1.1. For detailed information on full board review of early study termination application, **see SOP II-8.8.7**

4.5.5. *Communication of Results*

4.5.5.1. The PI is notified of the JEPeM-USM decision, noting JEPeM-USM action on the early study termination application through a letter.

4.5.6. *Files Management*

4.5.6.1. The Secretariat Staff files the early study termination application documents in the study protocol file folder. For electronic version, it will be stamped electronically.

4.6. Queries or Complaints

4.6.1. *Management of Submitted Queries or Complaints*

4.6.1.1. Queries and complaints, especially from research participants, are major considerations because they provide mechanisms that contribute both to maintaining transparency of JEPeM-USM decision-making processes, as well as empowerment of study participants.

4.6.1.2. Any JEPeM-USM personnel can receive a query or complaint. Action on queries and complaints is managed through the use of **JEPeM-USM FORM 3(I): QUERIES OR COMPLAINTS.** Each query or complaint received will be individually entered into this form by respective JEPEM-USM personnel, and then forwarded to the Secretariat for processing.

4.6.1.3. The Secretariat Staff logs the query or complaint into the **database.**

4.6.2. *Classification of Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary*

4.6.2.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary classifies queries as either full board or expedited review depending on the nature of the query and response needed.

4.6.2.2. Complaints are classified under full board review or expedited review.

4.6.3. *Review by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary and Primary Reviewers*

4.6.3.1. For submissions under expedited review, action is finalized at the level of the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary within **ten (10) working days**.

4.6.3.2. Submissions subject to full board review will be forwarded to the primary reviewers who will complete the review within **ten (10) working days**. In the event where primary reviewers are no longer available, new reviewers will be appointed by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary.

4.6.3.3. The Primary Reviewers accomplishes the review and returns the signed **JEPeM-USM FORM 3(I): QUERIES OR COMPLAINTS.**

4.6.3.4. The Secretariat Staff places the query or complaint in the agenda of the next JEPeM-USM meeting.

4.6.3.5. If necessary, the PI will be contacted to provide clarification.

4.6.4. ***Full Board Review of Study Participant Query or Complaint***

4.6.4.1. The Secretariat Staff distributes the completed **JEPeM-USM FORM 3(I): QUERIES OR COMPLAINTS** to JEPeM-USM Members along with the meeting agenda:

4.6.4.2. The JEPeM-USM deliberates on how best to address the concerns relevant to the query or complaint, and recommends a course of action.

4.6.4.3. The JEPeM-USM may request for clarification by email or interview from the PI.

4.6.4.4. For detailed information on full board review of queries or complaints, **see SOP II-8.8.8**

4.6.5. ***Communication of Results***

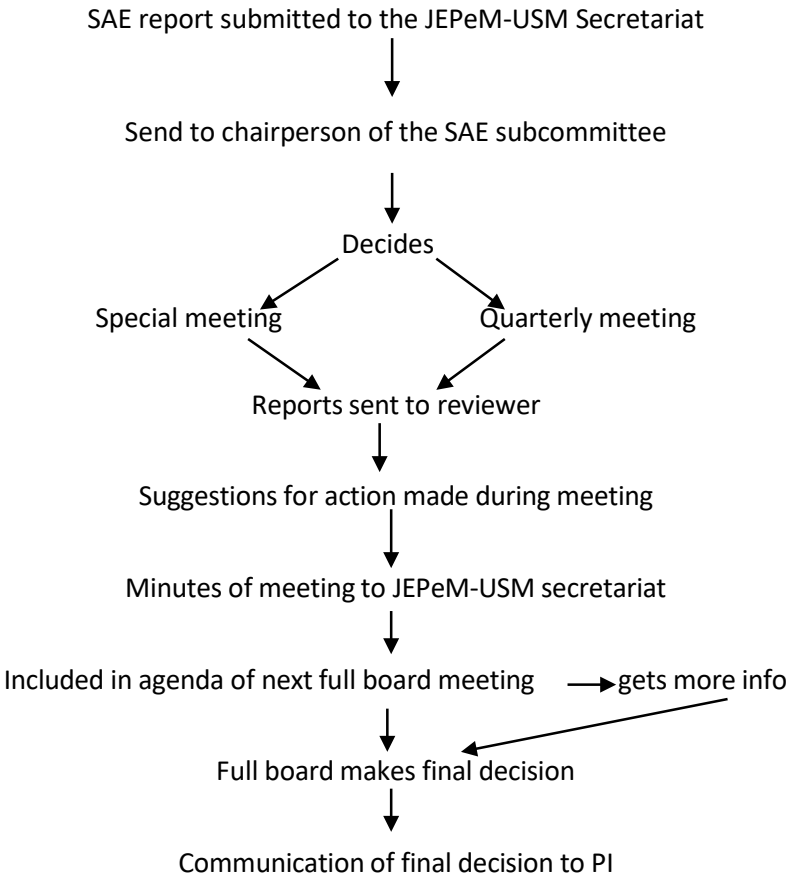
4.6.5.1. The JEPEM-USM responds to queries and complaints in writing after a course of action of appropriate response is identified whether through expedited or full board review.

4.6.5.2. The PI may be requested to provide additional information or submit additional documents.

4.6.6. ***Files Management***

4.6.6.1. The Secretariat Staff files the signed documents in the study protocol file folder. For electronic version, it will be stamped electronically.

5. Serious Adverse Event Reports Workflow



DETAILED INSTRUCTIONS

5.1. *Management of the SAE Report upon Submission*

5.1.1. Serious adverse events are events temporally associated with the subject' participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

Serious adverse events that are reported to the JEPeM-USM secretariat will be initially dealt with by a dedicated SAE subcommittee. The SAE subcommittee will meet on a quarterly basis (every three months) or when deemed necessary (special meeting).

5.1.2. The PI must report serious adverse advents to the JEPeM-USM in accordance with the **JEPeM-USM Guideline on Reporting Adverse Events (JEPeM-USM, GL01).**

5.1.3. Reporting of SAEs is facilitated through the submission of **JEPeM-USM FORM 3(G): SERIOUS ADVERSE EVENT/S REPORT**, together with the documents deemed relevant by the investigator to clarify information indicated in the report. This comprises the study protocol serious adverse event/s report package. If the PI submits a form similar to the FORM 3(G) (e.g. CIOMS form) this will be accepted as well and the PI does not have to transfer the data into FORM 3(G).

5.1.4. The Secretariat Staff assigned to the SAE Subcommittee checks the submission for completeness and gives acknowledgment of receipt of the received form to the PI or his/her representative.

5.1.5. The Secretariat Staff logs the date of submission on the database**.**

5.2. *Submission of SAE Package to SAE Subcommittee Chair*

5.2.1 Serious adverse event/s report packages received by the JEPeM-USM secretariat will be forwarded within **seven (7)** calendar days to the chair of the SAE subcommittee. The following documents will be submitted to the chair:

- The submitted form
- List of known ADRs as written in the Investigators' Brochure (latest version)

- Protocol Summary
- Investigators' Brochure (latest version)
- Other supporting documents, if necessary

5.2.2 The Chair of the SAE subcommittee classifies whether the SAE report will need urgent attention and requires a special SAE subcommittee meeting or whether it will be brought to the next quarterly SAE subcommittee meeting.

5.3 *SAE Subcommittee Meeting*

5.3.1 The SAE subcommittee will meet on a quarterly basis (every three months). SAE reports needing urgent action as decided by the Chair of the SAE subcommittee are brought to a special SAE Subcommittee Meeting.

5.3.2 The National Poison Management and Control Center may be requested to make further investigations if the SAE involves overdose or poisoning. A site visit may be conducted, in coordination with the PI, at the expense of the PI or sponsor.

5.3.3 Conduct of AE Subcommittee Meeting

5.3.2.1 The SAE report package comprising of the following documents is distributed to the respective AE Subcommittee Primary Reviewer(s) (1 or 2 based on the judgement of the chair of the SAE sub-committee) at least **ten (10) working days** before the panel meeting:

- The report form
- List of known ADRs as written in the Investigators' Brochure
- Protocol Summary
- Investigators' Brochure
- Other supporting documents, if necessary

5.3.2.2 The chair of the subcommittee places the SAE report on the agenda of the AE Subcommittee meeting.

5.3.2.3 The AE Subcommittee Primary Reviewers accomplish the review and bring their comments to the SAE subcommittee meeting.

5.3.2.4 The AE Subcommittee may recommend any of the following actions:

- *Uphold original approval with no further action required*
- *Request further information*
- *Recommendation for further action:*
  → Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;

→ Recommend implementation of additional procedures for protecting/safeguarding participants;
→ Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)
→Recommend suspension of the entire study

5.3.4 Presentation of AE Subcommittee Recommendations to full board

5.3.3.1 The AE Subcommittee Chair submits the minutes of the meeting that contain the recommendations of the AE Subcommittee to the JEPeM-USM secretariat and these will be included in the agenda of the next meeting of the full board of the JEPeM-USM.

5.3.3.2 The following documents are distributed to each full board member together with the agenda:

- SAE REPORT forms i.e **JEPeM-USM FORM 3(G) SERIOUS ADVERSE EVENT/S REPORT**
- AE Subcommittee recommendations as outlined in the minutes of the meeting(s) of the SAE subcommittee

5.3.5 Deliberation on Full Board Action: During the meeting, the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary calls for a decision on the SAE report with respect to the recommendations of the SAE Subcommittee. The JEPeM-USM may require any of the following actions:

- *Uphold original approval with no further action*
- *Request information*
- *Recommendation for further action according to recommendations of SAE subcommittee*

5.4 *Communication of Results*

5.4.1 The PI is notified of the Full Board decision, noting required action on the Serious Adverse Event/s Report through a letter. A copy of this letter will be sent to the chair of the SAE subcommittee.

5.5 *Files management*

5.5.1 After the SAE meeting all documents are returned the JEPeM-USM secretariat where they will be filed in the study protocol file folder. For electronic version, it will be stamped electronically.

6. Site Visit Workflow

The site visits will be performed by a specifically appointed subcommittee. The process will proceed according the following table.

ACTIVITY	RESPONSIBLE PERSON
Select study sites to visit ↓	JEPeM-USM Chairperson, Deputy Chairperson, Panel Chair, Member Secretary and Members
Chair of Site visit subcommittee will be informed ↓	Secretariat Staff
Notify PI of date of site visit ↓	Secretariat Staff
Create Site Visit Team ↓	Subcommittee Chair
Conduct Site Visit ↓	Site Visit Team
Present findings during full board meeting ↓	Site Visit Team
Communicate results of Site Visit and subsequent full board decision to PI ↓	Secretariat Staff
Manage Site Visit documents	Secretariat Staff

DETAILED INSTRUCTIONS

6.1. *Selection of Study Sites*

6.1.1. Study sites may be selected for Site Visits based on the following criteria:

- The nature of the study being conducted (i.e. high risk studies)
- Frequent non-submission or failure to submit continuing review requirements
- Reports of major protocol noncompliance
- Significant number of serious adverse events
- Reports of complaints from study participants
- Site visits may be conducted upon recommendation of the JEPeM-USM

6.1.2. Study sites may also be suggested for site visit upon recommendation of the JEPeM-USMAdverse Event Subcommittee.

6.1.3. A decision for Site Visit is deliberated on during a full board meeting of the JEPeM-USM.

6.2. ***Communication JEPEeM-USM– subcommittee - PI***

6.2.1. The Secretariat Staff prepares a Study Visit Package for each member of the site visit team, inclusive of the **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM** and a copy of the approved study protocol and related documents**.** A letter of notification that includes the reason for the site visit is forwarded together with these packages to the chair of the subcommittee for site visits.

6.2.2. Secretariat of JEPeM-USM informs the PI at least **ten (10) working days** before the scheduled visit through a letter. A copy of **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM** is attached to this letter.

6.2.3. The letter provides site visit schedule details and instructions on what the PI needs to prepare, such as documents and files that will be used for the site visit, as well as orderly preparation of the site.

6.3. ***Creation of a Site Visit Team***

6.3.1. A site visit team is organized for each site visit.

6.3.2. The members of this team are assigned by the Site Visit Sub-Committee Chair.

6.3.3. The site visit team should be composed of **at least two (2) members** of the committee for site visits.

6.3.4. The site visit team members are informed of their assignment through the issuance of **JEPeM-USM FORM 3(H): NOTICE OF SITE VISIT.**

6.3.5. The site visit team prepares by reviewing the contents of the study file and the requirements of **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM.** A pre-site visit meeting may be called by the chair of the subcommittee before the actual visit. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary may invite members of the JEPeM-USM to this meeting if it is deemed necessary.

6.4. *Conduct of Site Visit*

6.4.1. Upon arrival in the study site, the site visit team uses **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM** to do the following:

- Review the study protocol
- Review the informed consent documents and verify its approved version.
- Ask the PI or staff to explain the informed consent process
- Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved
- Verify security, privacy, and confidentiality of the documents at the study site
- Observe facilities in the study site
- Make an overall determination of the protection of the rights, safety, and welfare of human participants in the study

6.4.2. At the end of the visit, the site visit team will:

- Discuss the findings with the research team
- Solicit feedback

6.5. *Presentation of findings at JEPeM-USM Meeting*

6.5.1. The site visit team completes **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM** which should reflect the consensus opinion of the site visit team members, and submits it to the Secretariat not later than **ten (10) working** days after the site visit.

6.5.2. The Secretariat Staff logs the date of submission on the **SUBMISSIONS LOG [JEPeM-USM FORM 4(M)].**

6.5.3. During the meeting, the Secretariat Staff distributes the completed **JEPeM-USM FORM 3(F): SITE VISIT REPORT FORM** to JEPeM-USM Members along with the meeting agenda

6.5.4. The JEPeM-USM members deliberate on the implications of results of the site visit on the rights, safety, and welfare of the study participants; and make an overall determination of protocol compliance in the study site.

6.6. *Communication of results*

6.6.1. The PI is notified of the full board recommendations through a letter.

6.6.2. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

6.7. *Site Visit files management*

6.7.1. The Secretariat Staff includes the discussions in the minutes of the meeting and files the site visit documents in the study protocol file folder**.**

GUIDELINES ON REPORTING ADVERSE EVENTS

1. Objectives

This Guideline describes the obligation to report serious adverse events (SAEs). The purpose of this Guideline is to provide instructions on the review of initial and follow-up reports of SAEs occurring at clinical trial sites and offsite (non-USM site) for any study approved by JEPeM-USM.

Information on how reportable serious adverse events will be defined, identified and what procedures for reviewing and reporting will be followed are outlined in this Guideline.

2. Reporting Requirements and Procedure

2.1 Although the JEPeM-USM only requires the PI to report adverse events as defined in the **Timeline Requirements**, he/she is responsible for assessing, documenting, and tracking all SAEs in the research study, including new physical symptoms, regardless of who observed or became aware of the event.

2.2 The PI is also responsible for reporting SAEs to the proper regulatory agency as defined by applicable laws (eg: National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia).

2.3 The reporting requirements of other organizations (e.g. Sponsor, relevant non-Malaysian authorities like FDA) also must be completed and are not satisfied or precluded by submitting SAE Report to the JEPeM-USM. Likewise, submitting SAE Reports to other organizations (e.g., Sponsor, FDA) does not satisfy the reporting requirement to the JEPeM-USM.

2.4 The observed SAEs must be submitted using **JEPeM-USM FORM 3(G): SERIOUS ADVERSE EVENTS REPORT FORM**

3. Timeline Requirements

3.1. The Principal Investigator must report to the JEPeM-USM Committee members all SAEs according to the following timelines:

3.1.1. Deaths MUST be reported to the JEPeM-USM if they occur within seven (7) days of study intervention.

3.1.2. If the suspected expected/unexpected serious adverse event occurred onsite for initial report, it must be reported to the JEPeM-USM promptly, within no more than one (1) week (7 calendar days) of recognition/notification of the event.

3.1.3. If a suspected unexpected serious adverse event occurred offsite as part of a multi-site research project, it must be reported to the JEPeM-USM within 3 to 6 months of recognition/notification of the event.

4. Summary of Timeline Requirements for Reporting of PI

Event type	**Onsite or Off-site**	**Expected or unexpected**	**Reporting requirements**
Serious adverse event	Onsite	Either	Report within seven (7) calendar days using **JEPeM-USM Form 3(G): Adverse Events Report Form.**
Serious adverse event	Off-site	Either	CIOMS or equivalent form 3 – 6 months report with regular progress report and/or final report
Adverse event not serious	Onsite or offsite	Either	Report with regular progress report and/or final report

GLOSSARY

The following terminologies and definitions are to be used in the reporting of adverse events:

1. **Adverse event:** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events may also be psychological in nature.

2. **Onsite adverse event**: From the perspective of one particular institution engaged in a multicenter clinical trial, *on-site adverse events* are those adverse events experienced by subjects enrolled by the investigator(s) at that institution. In the context of a single-center clinical trial, all adverse events would be considered *on-site adverse events.* It also includes adverse events occurring on all JEPeM-USM approved clinical trials sites. If the PI is from USM and the study is JEPeM-USM-approved, study site is considered onsite even if the site is outside any USM campus.

3. **Off-site adverse event**: From the perspective of one particular institution engaged in a multicenter clinical trial, *offsite adverse events* are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.

4. **Possibly related to the research**: There is a reasonable possibility that the problem, event, incident, experience or outcome may have been caused by the procedures involved in the research.

5. **Serious Adverse Event:** Any adverse event temporally associated with the

subject's participation in research that meets any of the following criteria:

5.1 results in death;

5.2 is life-threatening (places the subject at immediate risk of death from the event as it occurred);

5.3 requires inpatient hospitalization or prolongation of existing hospitalization;

5.4 results in a persistent or significant disability/incapacity;

5.5 results in a congenital anomaly/birth defect; or

any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

6. **Suspected Unexpected Serious Adverse Reaction (SUSAR):** An adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g. as in Investigator's Brochure if product is unlicensed)

LIST OF ACRONYMS

AE	Adverse Events
AO	Administrative Order
CIOMS	Council for International Organizations of Medical Sciences
FDA	Food and Drug Administration
DOH	Department of Health
PI	Principal Investigator
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
USM	Universiti Sains Malaysia
JEPeM-USM	**J**awatankuasa **E**tika **Pe**nyelidikan **M**anusia

Study Protocol Amendment Submission Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:

A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the JEPeM-USM Committee that issued the ethical clearance or approval prior to the implementation of an amendment. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in A4 size paper; then date and sign this form before submission.

JEPeM CODE:USM/JEPeM/		
STUDY PROTOCOL TITLE:		
INITIAL APPROVAL DATE:	**EXPIRY DATE OF LAST APPROVAL:**	
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
AMENDMENT SUBMISSION DATE:		

1. **NO. OF AMENDMENT/S**:
2. **STATE NATURE OF STUDY PROTOCOL AMENDMENT** (cite study protocol section and page where amendment is found, for each amendment; use additional pages or expand this space electronically if necessary)

No	Original	Amendment	Page	Justification

3. **TYPE OF REVIEW**:

3.1. ☐ **EXPEDITED** REVIEW FOR AMENDMENTS THAT:

- Do not involve changes in study populations
- Do not involve the collection of stigmatizing information
- Do not change approved use of anonymized or archived samples
- Do not involve further recruitment of participants
- Involve study protocols previously classified under expedited review
- Are administrative in nature (such as contact details of study personnel)
- Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants

3.2. ☐ **FULL BOARD REVIEW** for any amendments not cited under EXPEDITED REVIEW

SIGNATURE OF PRINCIPAL INVESTIGATOR:

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW:

Signature_____

Name

RECOMMENDATIONS (for JEPeM use only) – for full board review only

Comments of Primary Reviewer

The risk/benefit ration of this study after the amendment is:

- ☐ Improved
- ☐ The same
- ☐ Worse

Recommended Action

- ☐ APPROVAL
- ☐ MINOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE CHAIR
- ☐ MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW
- ☐ DISAPPROVAL

PRIMARY REVIEWER Date:	Signature Name	
JEPeM-USM CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY Date:	Signature Name	

Continuing Review Application Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:

Ethical clearance or approval is typically granted for a period of one year (12 months). Continuing review is required to be done at least once a year, corresponding to the risk assessment of the study protocol. The frequency of continuing review is indicated in the Study Protocol Approval Letter. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form 60 days prior to expiry date. Obtain an electronic copy of this form and encode all information required in the space provided. Print the application in A4 size paper; then date and sign this form before submission.

Please write NA if the requested information is not applicable to your study

JEPeM CODE:USM/JEPeM/		
STUDY PROTOCOL TITLE:		
INITIAL APPROVAL DATE:	**EXPIRY DATE OF LAST APPROVAL:**	
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
APPLICATION SUBMISSION DATE: (to be filled out by JEPeM) <dd/mm/yyyy>		

1. START DATE:

1.1. Date of research site initialization: <dd/mm/yyyy>

1.2. Explanation, if not yet initialized as of date of this application: <reason/s>

2. ACTION REQUESTED:

2.1. ☐ Renewal: New participant accrual to continue

2.2. ☐ Renewal: Enrolled participant follow up only

2.3. ☐ Early Termination: Study protocol discontinued ahead of study indicated duration

2.4. ☐ Other (specify):

3. HAS THERE BEEN ANY AMENDMENT SINCE THE LAST REVIEW/APPROVAL?

3.1. ☐ No

3.2. ☐ Yes (Describe briefly and / or attach amendment approval letter)

4. HAS THERE BEEN ANY CHANGE IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?

4.1. ☐ No

4.2. ☐ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

5. HAS THERE BEEN ANY CHANGE IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document

5.1. ☐ No

5.2. ☐ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

6. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE COMMITTEE'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?

6.1. ☐ No

6.2. ☐ Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)

7. HAS ANY UNEXPECTED DISCOMFORT, COMPLICATION, OR SIDE EFFECT BEEN NOTED SINCE LAST REVIEW/ APPROVAL? 7.1. ☐ No 7.2. ☐ Yes (Summarize and indicate date/s of SUSAR report submission/s)
8. HAS THERE BEEN ANY NEW INTERVENTION OR METHOD IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL 8.1. ☐ No 8.2. ☐ Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)
9. HAS ANY INVESTIGATOR BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL? 9.1. ☐ No 9.2. ☐ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the JEPeM USM)
10. HAS ANY NEW COLLABORATING SITE (INSTITUTION) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL? 10.1. ☐ No 10.2. ☐ Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)
11. HAS ANY INVESTIGATOR DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL? 11.1. ☐ No 11.2. ☐ Yes (Append a statement of disclosure)
12. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL? 12.1. ☐ NONE: 12.2. ☐ DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s) 12.3. ☐ ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
13. HAVE THERE BEEN ANY UPDATES ON COVERAGE OF INSURANCE CERTFICATE (IF ANY) SINCE THE LAST REVIEW/APPROVAL? Attach an updated insurance certificate. 13.1. ☐ No 13.2. ☐ Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
14. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis. 14.1. ☐ No 14.2. ☐ Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
15. PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete) 15.1. <Component 1><Provide description as needed> 15.2. <Add components as necessary>
16. Note: If amendment has been made without the submission of study amendment form 3A, please submit this form together.
SIGNATURE OF PRINCIPAL INVESTIGATOR:
DATE SIGNED:

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW:

Signature:

Name:

Comments of Reviewer:

RECOMMENDED ACTION:

- ☐ Extension of original approval with no further action (Application received on or before expiry date)
- ☐ Extension of original approval with a warning statement (Application received after expiry date)
- ☐ PI to be called in Full Board meeting to seek further clarification (Application received more than 1 year after expiry date)
- ☐ Request information: (indicate information)
- ☐ Recommend further action: (indicate action)

PRIMARY REVIEWER	Signature	
Date:	Name	
JEPeM-USM CHAIRPERSON /DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY	Signature	
Date:	Name	

Final Report Form for Interventional Study

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:
This form is required upon completion of the study or closure of study site. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.

JEPeM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
STUDY PROTOCOL APPROVAL DATE:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
REPORT SUBMISSION DATE:		
1. Study Arms:		
2. Number of study participants in the beginning of the study:		
3. Number of participants at the end of the study:		
4. Number of participants who received the test articles:		
5. Summary of amendments to the original protocol (including dates of approval):		
6. Summary of SAE reported:		
7. Summary of anticipated risks (other than SAEs) documented in the conduct of study:		
8. Summary of SUSAR reported:		
9. Summary of unanticipated risks (others than SUSAR) documented in the conduct of study:		
10. Summary of participants' complaints or grievances documented regarding conduct of study:		
11. Summary of benefits documented:		
12. Summary of indemnifications (If Applicable):		
13. If terminated early, specify reason for termination:		
14. *Continuing Review Application Submission* dates with corresponding JEPeM USM action:		
15. Summary of study materials used (for non-clinical research):		
16. List of treatments or interventions:		
17. Study dose(s):		
18. Duration of the study:		
19. Study objectives and summary of results:		
20. List of informed consent form used (version/date) and attach most recent version: 21. Will this research published in 1 year time? Y/N		
DATE OF LAST REVIEW:		
SIGNATURE OF PI:		
DATE SUBMITTED:		
RECEIVED BY:		

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW: **Signature:** **Name:**	
Comments of Reviewer:	
RECOMMENDED ACTION: ☐ Approval ☐ Request information: (indicate information) ☐ Recommend further action: (indicate action)	
PRIMARY REVIEWER Date:	Signature Name
JEPeM-USM CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY Date:	Signature Name

Final Report Form for Non-Interventional Study

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:
This form is required upon completion of the study or closure of study site. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.

JEPeM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
STUDY PROTOCOL APPROVAL DATE:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
REPORT SUBMISSION DATE:		
1. Number of study participants planned:		
2. Number of participants at the end of the study:		
3. Summary of amendments to the original protocol (including dates of approval):		
4. Summary of participants' complaints or grievances documented regarding conduct of study:		
5. Summary of benefits documented:		
6. Summary of study materials used (for non-clinical research):		
7. Duration of the study:		
8. Study objectives and summary of results:		
9. List of informed consent form used (version/date) and attach most recent version:		
DATE OF LAST REVIEW:		
SIGNATURE OF PI:		
DATE SUBMITTED:		
RECEIVED BY:		

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW: **Signature:** **Name:**		
Comments of Reviewer:		
RECOMMENDED ACTION: ☐ Approval ☐ Request information: (indicate information) ☐ Recommend further action: (indicate action)		
PRIMARY REVIEWER Date:	Signature Name	
JEPeM-USM CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY Date:	Signature Name	

Study Protocol Noncompliance (Deviation or Violation) Report

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: ***This form refers to the requirements in ICH-GCP Sections 4.5: COMPLIANCE WITH PROTOCOL and 5.20: NONCOMPLIANCE. Obtain an electronic copy of this form and encode all information required in the space provided. Information submitted under this form is subject to full board review by the JEPeM-USM that issued ethical clearance or approval for the study. Print the report in A4 size paper; then date and sign this form before submission.***

Please write NA if the item is not applicable to your study.

JEPeM-USM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
REPORT SUBMISSION DATE:		
1. NATURE OF REPORT 1.1. ☐ **MINOR PROTOCOL DEVIATION** (*nonsystematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*) **1.2.** ☐ **MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION** *(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)*		
2. DESCRIPTION OF REPORTED DEVIATION/VIOLATION:		
3. DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:		
4. SPONSOR ASSESSMENT OF SEVERITY: **4.1.** ☐ MAJOR **4.2.** ☐ MINOR		
5. DESCRIPTION OF SPONSOR CORRECTIVE ACTION:		
DATE OF DEVIATION/VIOLATION:		
REPORTED BY:		
DATE OF REPORT:		
PI SIGNATURE:		

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW: **Signature:** **Name:**	
Comments of Reviewer:	
RECOMMENDED ACTION: ☐ Uphold original approval with no further action ☐ Request information: (indicate information) ☐ Recommend further action: (indicate action)	
PRIMARY REVIEWER Date:	Signature Name
JEPeM-USM CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY Date:	Signature Name

Early Study Termination Application Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: ***This form is required to apply for premature termination or suspension of a study and refers to ICH-GCP Section 4.12: PREMATURE TERMINATION OR SUSPENSION OF A TRIAL. Obtain an electronic copy of this form and encode all information required in the space provided. Print the application in A4 size paper; then date and sign this form before submission.***

JEPeM-USM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
STUDY PROTOCOL APPROVAL DATE:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
APPLICATION SUBMISSION DATE:		
1. START DATE:		
2. PROPOSED TERMINATION DATE:		
3. PARTICIPANTS ENROLLED TO DATE:		
4. SUMMARY OF RESULTS TO DATE:		
5. REASON FOR TERMINATION with JUSTIFICATION (eg: budget, safety issues, unforeseen circumstances)		
6. ACTION PLAN:		
7. LEGAL IMPLICATIONS: YES/NO (If YES, please elaborate)		
SIGNATURE OF PI:		
DATE OF APPLICATION:		

RECOMMENDATIONS (by JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member secretary)

FULL BOARD REVIEW OR EXPEDITED REVIEW: **Signature:** **Name:**
Comments of Reviewer:
RECOMMENDED ACTION: ☐ Approval ☐ Request information: (indicate information) ☐ Recommend further action: (indicate action)
PRIMARY REVIEWER Signature Date: Name
JEPeM-USM CHAIRPERSON/DEPUTY CHAIRPERSON/PANEL CHAIR/MEMBER SECRETARY Signature Date: Name

Site Visit Report Form

JEPeM-USM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
SITE VISIT DATE:		

1. Total participants expected:

2. Total participants enrolled:

3. Are site facilities appropriate?

3.1. ☐ YES
3.2. ☐ NO
3.3. COMMENTS:

4. Are informed consent documents updated to the version approved by the JEPeM-USM?

4.1. ☐ YES
4.2. ☐ NO
4.3. COMMENTS:

5. Is there any SAE/SUSAR reports not previously reported to the JEPeM-USM?

5.1. ☐ YES
5.2. ☐ NO
5.3. COMMENTS

6. Is there any event of protocol noncompliance not previously reported to the JEPeM-USM?

6.1. ☐ YES
6.2. ☐ NO
6.3. COMMENTS

7. Are investigation products secured adequately?

7.1. ☐ YES
7.2. ☐ NO
7.3. COMMENTS

8. Are study documents secured adequately?

8.1. ☐ YES
8.2. ☐ NO
8.3. COMMENTS

9. Are all other JEPeM-USM approved documents (e.g. advertisements) used in accordance with the approved study protocol?

9.1. ☐ YES
9.2. ☐ NO
9.3. COMMENTS

10. Are there any significant findings in this visit that could affect participant's/subject's rights, safety or welfare

10.1. ☐ YES
10.2. ☐ NO
10.3. COMMENTS

11. Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects?

11.1. ☐ ADEQUATE
11.2. ☐ INADEQUATE
11.3. COMMENTS

12. Are there further actions or queries resulting from this site visit?

12.1. ☐ YES
12.2. ☐ NO
12.3. COMMENTS

13. Additional remarks/feedback from researchers/plans for improvement

COMPLETED BY THE FOLLOWING SUBCOMMITTEE MEMBERS:		
NAME	**SIGNATURE**	**DATE**
Name 1		
Name 2		
Name 3		

RECOMMENDED ACTION: (For JEPeM-USM use only) ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION: (specify) ☐ RECOMMEND FURTHER ACTION: (specify)	
JEPeM-USM SECRETARY Date:	Signature Name
JEPeM-USM CHAIRPERSON Date:	Signature Name

Serious Adverse Event/s Report

Principal Investigator:	JEPeM-USM Code: USM/JEPeM/	
Study Protocol Title:		
Name of the study medicine/device	Report Date: ☐ Initial ☐ Follow-up Onset date:	
Sponsor:	Date of first use:	
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth:	Weight: kg	Height: cm
Relevant medical history and concurrent conditions:		

I. REACTION INFORMATION:

_____ (use CIOMS definition) List all relevant tests/ lab data:	Check all appropriate to adverse reaction: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity ☐ Life threatening

II. SUSPECT DRUG/S INFORMATION:

Suspect drug/s (include generic name)		Did reaction abate after stopping drug? ☐ Yes ☐ No ☐ NA
Daily dose/s:	Route's of administration:	Did reaction appear after reintroduction? ☐ Yes ☐ No ☐ NA
Indication/s for use:		
Therapy date/s: (from/to)	Therapy duration:	

Is this reaction ☐ Unexpected ☐ Expected	
Treatment given for Adverse Event:	
Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System) ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable	
Outcome of reaction/event at the time of last observation: ☐ Recovered ☐ Recovering with sequelae ☐ Death ☐ Recovering ☐ Not recovering ☐ Unknown	

III. CONCOMITANT DRUG/S AND HISTORY:

Concomitant drug/s and dates of administration (exclude drug used to treat reaction)
Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER'S INFORMATION:

Name and address of manufacturer		
Manufacturer control no.		
Date received by manufacturer:	Report source ☐ Study ☐ Literature ☐ Health professional	
Date of this report:	Report type ☐ Initial ☐ Follow-up	

RECOMMENDED ACTION by SAE committee:

☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION

☐ REQUEST INFORMATION: (indicate information)

☐ RECOMMEND FURTHER ACTION: (indicate action)

JEPeM-USM SECRETARY	Signature	
Date:	Name	
JEPeM-USM CHAIRPERSON	Signature	
Date:	Name	

UNIVERSITI SAINS MALAYSIA

SAE REVIEWER REPORT FORM : Local Cases

REPORT SUMMARY							
Protocol / Study No.:				Principal Investigator:			
Protocol / Study Title:							
Date of Report	Date Received by SAE S/com.	Subject number	Event number	Type of Report 1. Initial 2. F/UP	Type of SAE*(8-12 CIOMS)	Outcome of event/reaction (Date)	Causality assessment by investigator (using WHO-UMC Causality Assessment System) 1. Certain 2. Probable 3. Possible 4. Unlikely 5. Unclassifiable

NOTES:

*Type of SAE (8-12 CIOMS):

1.Patient died	2.Involved or prolonged inpatient hospitalization	3.Involved persistent or significant disability or incapacity	4. Life threatening	5. Congenital anomaly	6. Other

** CTSUR Line Listing not updated yet. (CTSUR: Clinical Trial Severe and Unexpected Reactions)
NAc : Not accessible

RECOMMENDATIONS OF SAE SUB-COMMITTEE
(may tick more than one option)

- ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION
- ☐ REQUEST ADDITIONAL INFORMATION: (Indicate Information)
- ☐ RECOMMEND FURTHER ACTION:
  - ◯ Modification of subject inclusion and exclusion criteria to mitigate the newly identified risks
  - ◯ Modification of informed consent to include a description of newly identified risks
  - ◯ Implementation of additional procedures
  - ◯ Suspension of enrollment of new subject
  - ◯ Suspension of research procedures
  - ◯ Suspension of the entire study
  - ◯ Sponsor to update CTSUR Line Listing

_____
Signature of Reviewer 1

_____
Signature of Reviewer 2

_____
Printed Name of Reviewer 1

_____
Printed Name of Reviewer 2

Date:

Date:

< dd/mm/yyyy>

<NAME OF SITE VISIT SUBCOMMITTEE MEMBER>
Address

Re: <STUDY PROTOCOL TITLE> <JEPeM-USM CODE>
Dear **< SITE VISIT SUBCOMMITTEE MEMBER>**:

We wish to inform you that the JEPeM-USM has appointed you to be a subcommittee member of the Site Visit Team responsible for verifying compliance of the study site with JEPeM-USM approved protocol and related documents, such as, contents of the informed consent form, etc.

As the members of the Subcommittee, your responsibilities include the following:

1. Review the study protocol and the ICF (note: make sure that the site is using the most recent version)
2. Review the post-approval documents (note: make sure that the site is using the most recent version)
3. Ask the PI, staff or subjects to explain the informed consent process
4. Ensure security, privacy, and confidentiality of the documents at the study site
5. Discuss the findings with the research team
6. Solicit feedback from the study site

The details of the Site Visit are as follows:

Date	
Time	
Study Site	
Address	
Protocol Title	
PI	

If you have any questions regarding the information outlined in this notification, you may visit the JEPeM-USM Secretariat at the JEPeM-USM Office, email jepem@usm.my, or call telephone number 09-7672352/2354 for assistance.

Thank you and best regards.

Very truly yours,

Name and Signature
Chairperson, JEPeM-USM USM

Cc Chairperson of Site Visit Sub Committee
JEPeM-USM

< dd/mm/yyyy>

<NAME OF PI>
Address

Re: <STUDY PROTOCOL TITLE> <JEPeM-USM CODE>
Dear **< NAME OF PI>**:

We are pleased to inform you that the JEPeM-USM has selected your study site to be visit by our Subcommittee Members of the Site Visit Team which is responsible for verifying compliance of the study site with JEPeM-USM approved protocol and related documents, such as, contents of the informed consent form, etc.

The details of the Site Visit are as follows:

Date	
Time	
Study Site	
Address	
Protocol Title	
PI	

If you have any questions regarding the information outlined in this notification, you may visit the JEPeM-USM Secretariat at the JEPeM-USM Office, email jepem@usm.my, or call telephone number 09-7672352/2354 for assistance.

Thank you and best regards.

Very truly yours,

Name and Signature
Chairperson, JEPeM-USM USM

Cc Chairperson of Site Visit Sub Committee
JEPeM-USM

Queries or Complaints

INSTRUCTIONS: ***This form can be accomplished by any JEPeM-USM personnel or members who receive queries, complaints, or grievances pertaining to any study protocol under the responsibility of the JEPeM-USM. Information reported in this form is processed as a protocol-related submission. This form should be printed in A4 size paper and duly signed by the personnel accomplishing this report.***

JEPeM-USM CODE: USM/JEPeM/		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
DATE RECEIVED:		
1. **RECEIVED BY (JEPeM-USM Personnel) :**		
2. REQUEST DELIVERED THROUGH: 2.1. ☐ Telephone 2.2. ☐ Fax No 2.3. ☐ Mailed letter dated: 2.4. ☐ E-mail dated: 2.5. ☐ Walk-in (indicate date/time) 2.6. ☐ Other, specify:		
3. PERSON LODGING THE QUERY OR COMPLAINT 3.1. **<TITLE, NAME, SURNAME>** 3.2. **Address:** 3.3. **Telephone**: 3.4. **Mobile:** 3.5. **Email:**		
4. CONNECTION/RELATION OF PERSON TO THE STUDY PROTOCOL 4.1. **Study participant** 4.2. **Other: <specify>**		
5. PARTICIPANT CONCERNS 5.1. ☐ Query (**specify**) 5.2. ☐ Complaint (**specify**) 5.3. ☐ Others (**specify**)		
6. REFERRED TO 6.1. ☐ Full Board Review by Panel 6.2. ☐ Expedited Review at the level of the Chair		

7. Signature of JEPeM-USM Personnel:	
JEPeM-USM SECRETARY	
	Signature _____
Date:	Name
JEPeM-USM CHAIRPERSON	
	Signature _____
Date:	Name