

 	<p><b>JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA</b></p> <p><b>II. PROTOCOL REVIEW</b></p>
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## 1.0 OBJECTIVES

This SOP describes how JKEUPM Secretariat manages study protocol submission from initial submission and/or resubmission to panel action, including review classifications and panel review assignments. This SOP further aims to provide guidance to how the reviewers evaluate a study protocol submitted to the JKEUPM either for the first time (initial submission) or with modifications per JKEUPM Panel recommendations (resubmissions).

## 2.0 SCOPE

The JKEUPM reviews research conducted by members of the faculty, students and employees of UPM.

## 3.0 RESPONSIBILITIES

It is the responsibility of the Secretariat Staff to manage study protocol submission and process the submission.

It is the responsibility of JKEUPM Chair/Member Secretary to decide whether the study protocol is for full board review or for expedited review and is responsible for assigning primary reviewers. Member Secretary may assign primary reviewers based on their expertise.

It is the responsibility of the assigned reviewers to check the completeness of the study protocol delivered to them, systematically review the study protocol, write their comments in the JKEUPM application form (FORM 2.3)\*attach protocol review checklist (for both Primary and Layperson reviewers) and include consideration of relevant guidelines when doing the review, and present findings in the full board panel meeting (for full board review study protocols).

The Principal Investigator (PI) is responsible for submitting a complete set of documents to the JKEUPM. If the research involves student project, then the PI would be the main supervisor of the student.

## 4.0 INITIAL REVIEW WORKFLOW

### 4.1 Receipt and management of study protocol submission

- 4.1.1 A study protocol for initial review must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in **JKEUPM FORM 2.1-APPLICANT CHECKLIST**. For Clinical Trial, Checklist for clinical trial **JKEUPM FORM 2.2** has to be submitted.

- 4.1.2 The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist.
- 4.1.3 Incomplete or incorrect submissions will not be accepted and will be returned to Principal investigator (PI).
- 4.1.4 All clinical trials must be registered with National Medical Research Registry (NMRR), including projects carried out at non Ministry of Health Malaysia facilities. All the registration numbers should be included in the JKEUPM application form.

## 4.2 Classification of submission

- 4.2.1 The JKEUPM Chair/Member Secretary classifies the study protocol review pathway as either Expedited Review or Full Board Review filtered through the following criteria for Expedited Review:
  - a. The research poses low risk.
  - b. The study does not involve vulnerable populations.
  - c. The study does not involve the collection of stigmatizing information.
  - d. The study uses anonymized or archived sample.
  - e. Protocols involving interviews/ questionnaires/ survey/group work/ conversations of a non-confidential nature not likely to be detrimental to the status or interests of subjects, and not likely to offend the sensibilities and sensitivities of subjects.
  - f. Those that involve collection of biological samples by non-invasive means (e.g., collection of body fluids or excreta, buccal or throat swab, collection of hair or nail clippings).
  - g. Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely used in clinical practice and using medical devices approved by national regulatory authorities.
  - h. Research involving data, documents or specimens that have already been collected or will be collected for ongoing medical treatment or investigation.

Under usual circumstances, the time taken from submission of study protocols to approval is approximately **60 calendar days** taking into consideration the protocol revision by the PI and second review by reviewers.

- 4.2.2 Study protocols that do not meet the criteria for expedited review are classified under full board review.
- 4.2.3 The following study protocols are generally exempted from review:
  - a. Research involving information freely available in the public domain. For example, published biographies, newspaper accounts of an individual's activities and published minutes of a meeting.

- b. Research involving anonymised records and data sets that exist in the public domain.
- c. Studies of public behaviour that are purely observational (non-invasive and non-interactive), unless the recorded observations identify individuals (names, photographs) which could place them at risk of harm, stigma or prosecution.
- d. Research involving the use of non-sensitive, completely anonymous educational tests, survey and interview procedures when the participants are not defined as "vulnerable" and participation will not induce undue psychological stress or anxiety.
- e. Research involving the use of educational tests, survey and interview procedures on human participants in the public arena.

However, JKEUPM will have the final say whether or not ethics review is required.

### 4.3 Assignment of Primary Reviewers

- 4.3.1 The JKEUPM Chair/ Member Secretary assign one (1) scientific reviewer and one (1) or layperson as primary reviewers of the study protocol. Reviewers are selected on the basis of their expertise. The scientific/ medical reviewer is tasked to review technical soundness and related ethical issues while the layperson reviewer is tasked to review the informed consent process and forms.
- 4.3.2 The Secretariat Staff sends the study protocol to the primary reviewers once they are assigned.

### 4.4 Study Protocol Review

- 4.4.1 The Secretariat Staff sends study protocols to primary reviewers for full board and expedited review within **three (3) calendar days** after receipt of protocols.
- 4.4.2 Primary reviewers check for completeness of the documentation and information about the PIs, study sites and other documents required.
- 4.4.3 For both full board and expedited review study protocols, the primary reviewers return the reviewed protocols to the Secretariat Staff within **fourteen (14) calendar days** from receipt of protocols.
- 4.4.5 In the event the primary reviewers failed to meet the deadline, the secretariat will issue a reminder and give an extension of **seven (7) calendar days**. Failing which, the study protocol will be assigned to new primary reviewers, who will be given **seven (7) calendar days**.
- 4.4.6 For expedited review study protocols, the Secretariat Staff will notify the PI of the decision. For full board review protocols, PI will be notified of the decision after the meeting. The PI will have to amend the protocols according to the reviewer's suggestion.

4.4.7 The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are:

- a. RECOMMEND FOR APPROVAL
- b. MINOR MODIFICATIONS (Member Secretary to Review)
- c. MINOR MODIFICATIONS (Primary Reviewer/ Layperson to Re-review)
- d. MAJOR MODIFICATION (which require full board deliberation)
- e. NOT RECOMMENDED

4.4.8 The primary reviewers of full board study protocols present their findings in the panel meeting where panel action is deliberated.

4.4.9 The PI or co-investigator is required to attend the full board meeting to present their study protocol.

**4.5 Inquiry or Appeals of JKEUPM Decisions**

4.5.1 Decision made by JKEUPM is final.

**5.0 FULL BOARD MEETING WORKFLOW**

<b>Activity</b>	<b>Responsibility</b>
Set regular meeting schedule ↓	Chair/Member Secretary/ /Secretariat Staff
Distribute meeting agenda ↓	Secretariat Staff
Prepare meeting materials ↓	Secretariat Staff
Determine quorum ↓	Secretariat Staff
Call the meeting to order ↓	Chair
Confirm/Certify quorum ↓	Member Secretary
Declare conflict of interest ↓	Chair/ Member Secretary/Panel Members
Read and approve the minutes ↓	Chair/ Member Secretary/Panel Members
Review initial study protocol submissions and resubmissions ↓	Chair/ Member Secretary/Panel Members
Review post-approval submissions (including SAEs) based on the PASC meeting minute ↓	PASC Chair/Chair/ Member Secretary/Panel Members

Review report of results of expedited review ↓	Chair/ Member Secretary/Panel Members
Adjourn meeting ↓	Chair
Collect, store, and dispose meeting materials	Secretariat Staff

**5.1 Regular meeting schedule**

- 5.1.1 The JKEUPM Chair/ Member Secretary/Secretariat Staff must set its regular monthly meeting, e.g., “first Monday” of the month to facilitate preparations and regular attendance of Panel Members.
- 5.1.2 The Secretariat Staff confirms venue reservation for the scheduled meeting date and time **seven (7) calendar days** before the meeting through email.
- 5.1.3 The Secretariat Staff ensures that the venue, equipment, and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment replacement or purchase of necessary supplies.

**5.2 Distribution of the Meeting Agenda**

- 5.2.1 The Secretariat Staff distributes the meeting agenda together with the minutes of the previous meeting and related study protocols to meeting attendees at least **seven (7) calendar days** before the panel meeting through email.

**5.3 Determination of quorum**

- 5.3.1 Quorum is defined as the presence of minimum 50% of panel members, of whom are described as follows:
  - a. Scientific and/or medical member(s) with expertise on the study protocols being reviewed.
  - b. At least one (1) layperson.
  - c. \*At least one (1) member independent of the institution.
  - d. Representation of both female and male members.

\*An independent layperson can constitute quorums of both layperson and independent member

- 5.3.2 During the meeting, the Member Secretary determines quorum viability and informs the Chair to indicate readiness to call the meeting to order.

**5.4 Calling the meeting to order and completion of required procedures prior to review proper**

- 5.4.1 The Chair, or a designated member in the Chair’s absence, calls the meeting to order upon confirmation of quorum by the Member Secretary.

- 5.4.2 The JKEUPM also allows, at the discretion of the Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe JKEUPM meetings. Non-members (who are not PIs) attending any JKEUPM Panel Meeting are required to sign a **JKEUPM FORM 1.4: NON DISCLOSURE OF CONFIDENTIAL INFORMATION AND CONFLICT OF INTEREST**
- 5.4.3 The Secretariat Staff documents the proceedings of the meeting under the supervision of the Member Secretary, as soon as the meeting is called to order by Chair, noting the time. The Secretariat Staff documents the development of the agenda, specifically all board opinions and action with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator.
- 5.4.4 The Chair calls upon the Member Secretary to formally confirm quorum by citing the attendance requirements.
- 5.4.5 The Chair calls for declaration of Conflict of Interest (COI) in respect of any study protocol or submission scheduled for review. Members declaring COI are documented by the Member Secretary. The Chair instructs the members who declared COI to recuse themselves from the deliberation of the respective study protocol for which the COI declaration was made.
- 5.4.6 The Chair presides over the review of the Minutes of the previous meeting. A declaration of motion for approval can be made by a member and then seconded by another member. The Chair then declares approval of the Minutes of the previous meeting.
- 5.4.7 The Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat Staff for inclusion in the Minutes of the current meeting.
- 5.4.8 Full board review of study protocol and study protocol-related submissions typically includes review of the following:
- a. Study Protocol Submissions
    - i. Resubmission or Study Protocols for Modification.
    - ii. Clarificatory Interview.
- 5.4.9 The Chair may allow some modifications of the sequence of review in urgent circumstances. For example, if a clarificatory interview is included in the agenda, the panel may opt to move this up in the review sequence.
- 5.4.10 The Chair instructs the member who had previously declared conflict of (COI) to recuse himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such panel members may be called in by the panel to answer

questions to assist in the board in arriving at a board action, but under no circumstances participate in the decision.

## 5.5 Discussion of initial study protocol submissions and resubmissions

- 5.5.1 For initial review, the Panel Chair calls the primary reviewers to present findings on respective study protocols.
- 5.5.2 The scientific primary reviewer is instructed to focus presentation of findings on scientific soundness and its impact on human subject protection, while the layperson primary reviewer is instructed to focus presentation of findings on the informed consent process and informed consent form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies.
- 5.5.3 The Panel Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.
- 5.5.4 It is compulsory for the PI or other study team members to briefly explain their study protocols before the panel followed by question and answer session. Students are allowed to present the study protocols, however, the presence of their supervisor or co-supervisor is mandatory.
- 5.5.6 The Chair calls for any of the following actions and documented in form 2.6:
- a. Approved
  - b. Minor Modification (Member Secretary to Review)
  - c. Minor Modification (Primary Reviewer to Re-Review)
  - d. Major Modification, (which require full board deliberation)
  - e. Not approved
- 5.5.7 JKEUPM allows investigators and other resource persons (such as an Independent Consultant commissioned by JKEUPM or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the panel meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the board).
- 5.5.8 All revised study protocols should be submitted to the secretariat within **thirty (30) calendar days** from the date of letter/notification containing reviewer's comments. However, maximum period of **sixty (60) calendar days** is given for clinical trials protocol. Researchers are allowed to request for extension in writing.
- 5.5.9 A reminder will be issued to the PI fourteen **(14) calendar days** before the correction due date. In the case where the PI fails to collect the review from the secretariat, a notification will be issued after **seven (7) calendar days**.

5.5.10 An approval letter for both full board and expedited reviews which identified the study protocol reference number, the documents reviewed and dates for the decision will be issued to the PI within **seven (7) calendar days**.

5.5.11 A rejection letter which identifies the study protocol reference number, the documents reviewed and dates for the decision will be issued to the PI whose study protocols are not approved by JKEUPM within **seven (7) calendar days**.

## **5.6 Discussion of post-approval submissions**

5.6.1 The Chair of the Post-Approval Subcommittee will present the outcome of the PASC meeting, at the Full Board meeting. The presentation includes the following:

- a. Call to Order
- b. Attendance
- c. Confirmation of the minutes of the last meeting
- d. Matters arising from the minutes of the last meeting
- e. Protocol amendment
- f. Study Progress Report
- g. SAEs or SUSARs Reports
- h. Deviation / Violation of Protocol)
- i. Study Final Report
- j. Other Matters
- k. Adjournment

## **5.7 Review of results of Expedited Review**

5.7.1 The Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review. This report is being presented for the information of the members, and is not meant to generate discussion for board action unless serious issues emerge during this presentation, which is considered an exception.

## **5.8 Adjournment of the meeting**

5.8.1 Before closing the meeting, the Chair calls for any non-study protocol matters that need attention or action, as the need arises.

5.8.2 With no further matters for discussion, the Chair formally adjourns the meeting, with the time noted by the Secretariat Staff.

## **5.9 Collection and storage or disposal of meeting materials**

5.9.1 The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting.

5.9.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files.



**6.0 SPECIAL MEETINGS WORKFLOW**

Activity	Responsibility
Prepare for conduct of special meeting ↓	Secretariat Staff
Conduct special meeting ↓	Panel Chair/Panel Secretary/Panel Members
Collect, store, and dispose meeting materials	Secretariat Staff

**6.1 Preparation for Conduct of Special Meeting**

6.1.1 A special meeting may be called by the Chair or is proposed by a member of JKEUPM.

6.1.2 The decision to call a special meeting is based on the following criteria:

- a. Urgent issues (if delay will affect or have impact on the public benefit, national economy, etc.).
- b. Occurrence of unexpected serious adverse events.
- c. Life and death situations.
- d. Other similar situations at the discretion of the chair.

6.1.3 The Secretariat informs the JKEUPM members, including the invited persons, about the special meeting.

**6.2 Conduct of Special Meeting**

6.2.1 Quorum is defined as the presence of minimum 50% of panel members, of whom are described as follows:

- a) Scientific and/or medical member(s) with expertise on the study protocols being reviewed.
- b) At least one (1) layperson.
- c) \*At least one (1) member independent of the institution.
- d) Representation of both female and male members.

\*An independent layperson can constitute quorums of both layperson and independent member.

6.2.2 A special meeting may be conducted between the members through tele/video conference.

6.2.3 The meeting is conducted in the same sequence as full board review with similar corresponding actions.

### **6.3 Collection and storage or disposal of meeting materials**

6.3.1 The Secretariat Staff collects all meeting materials, including the Documentation collected for the Minutes of the meeting.

6.3.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files.