

	JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA
	2. PROTOCOL REVIEW

2.1 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).

2.2 SCOPE

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

2.3 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 Informed Consent 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.

2.4 INITIAL REVIEW WORKFLOW

2.4.1 Receipt and management of study protocol submission

- 2.4.1.1 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.
- 2.4.1.2 The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist **within 2 days of receiving them**, and will sign/initial the document as evidence of acceptance.
- 2.4.1.3 Incomplete or incorrect submissions will not be accepted and will be returned to the Principal investigator (PI).
- 2.4.1.4 All clinical trials conducted locally 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 before ethics approval being granted.
- 2.4.1.5 All research projects using Ministry of Health Malaysia facilities are required to obtain MREC approval. The approval needs to be submitted to the Deputy Dean of Research office of each faculty for its record keeping. This is to ensure that the office will be aware that its faculty staff has obtained ethics approval from IRB other than JKEUPM.
- 2.4.1.6 This includes all research projects using other institutions that have their own IRB. For research conducted in facilities other than UPM and **approved by the relevant ethics committees**, approval from JKEUPM is not necessary.
- 2.4.1.7 Approval from JKEUPM is not necessary for research conducted by UPM students abroad that has obtained ethical approval from the local IRB. However, JKEUPM will still accept submission from students to get ethical approval from JKEUPM to conduct a study abroad, in the event it becomes necessary.

2.4.2 Classification of submission

- 2.4.2.1 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 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.

Time revision timeline for all protocols is **sixty (60) working days** after receiving the letter/notification of the review.

2.4.2.2 Study protocols that do not meet the criteria for expedited review are classified under full board review.

2.4.2.3 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.

The exemption of protocol will be screened by the member secretary and later sent for review to a suitable primary reviewer. And the outcome will be discussed in the board meeting whether to approve or disapprove the exemption based on the primary reviewer recommendation.

2.4.2.4 Members secretary will determine the type of review and appointment of primary reviewers within 3 days after receiving from the secretariat.

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

2.4.3 Assignment of Primary Reviewers

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

2.4.4 Study Protocol Review

- 2.4.4.1 The Secretariat Staff sends study protocols to primary reviewers for full board and expedited review within **five (5) working days** after receipt of protocols.
- 2.4.4.2 Primary reviewers check for completeness of the documentation and information about the PIs, study sites and other documents required.
- 2.4.4.3 For both full board and expedited review study protocols, the primary reviewers return the reviewed protocols to the Secretariat Staff within **ten (10) working days** from receipt of protocols.
- 2.4.4.4 In the event the primary reviewers failed to meet the deadline, the secretariat will issue a reminder and give an extension of **seven (7) working days**. Failing which, the study protocol will be assigned to new primary reviewers, who will be given **seven (7) working days**.
- 2.4.4.5 Regular monitoring every **three (3) months** will be done by the Secretariat to monitor the timeline of the review process and the study protocol which does not meet above requirements will be assigned to new primary reviewers
- 2.4.4.6 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 revise the protocols according to the reviewer's suggestion.
- 2.4.4.7 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 (Full Board Review only)
 - b. APPROVAL (Applicable for Expedited Review only)
 - c. MINOR MODIFICATION (Member Secretary to Review/Primary Reviewer/ Informed Consent Reviewer to Re- review)
 - d. MAJOR MODIFICATION (require full board deliberation/Primary Reviewer/ Informed Consent Reviewer to Re- review)

e. RECOMMEND TO DISAPPROVE

- 2.4.4.8 The primary reviewers of full board study protocols present their findings in the panel meeting where panel action is deliberated.
- 2.4.4.9 The PI or co-investigator is required to attend the full board meeting to present their study protocol.

2.4.4.10 The decision of protocol review will be emailed to the PI by the Secretariat. The decision email will include information on:

- a. The date of the full board meeting
- b. The list of documents evaluated.
- c. The list of documents evaluated.
- d. The types of modification (minor or major)

2.4.4.11 The rejection letter will include information on:

- a. The names and specific identification numbers of each document reviewed.
- b. The list of members who attended the full board meeting.

2.4.5 Inquiry or Appeals of JKEUPM Decisions

2.4.5.1 Decision made by JKEUPM is final. However, provision for appealing JKEUPM decision are permissible and researchers should submit a formal request for an appeal within **fourteen (14) working days** of the decision. The appeal shall be discussed at the next JKEUPM meeting.

2.5 FULL BOARD MEETING WORKFLOW

Activity	Responsibility
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

2.5.1 Regular meeting schedule

2.5.1.1 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.

2.5.1.2 The Secretariat Staff confirms venue reservation for the scheduled meeting date and time **five (5) working days** before the meeting through email.

- 2.5.1.3 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.

2.5.2 Distribution of the Meeting Agenda

- 2.5.2.1 The Secretariat Staff distributes the meeting agenda together with the minutes of the previous meeting and related study protocols to meeting attendees at least **five (5) working days** before the panel meeting through email.

2.5.3 Determination of quorum

- 2.5.3.1 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.

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

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

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

- 2.5.4.2 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**

- 2.5.4.3 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.

- 2.5.4.4 The Chair calls upon the Member Secretary to formally confirm quorum by citing the attendance requirements.
- 2.5.4.5 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.
- 2.5.4.6 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.
- 2.5.4.7 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.
- 2.5.4.8 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.
- 2.5.4.9 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.
- 2.5.4.10 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.

2.5.5 Discussion of initial study protocol submissions and resubmissions

- 2.5.5.1 For initial review, the Panel Chair calls the primary reviewers to present findings on respective study protocols.

- 2.5.5.2 The scientific primary reviewer is instructed to focus presentation of findings on scientific soundness and its impact on human subject protection, while the informed consent 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.
- 2.5.5.3 The Panel Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.
- 2.5.5.4 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.
- 2.5.5.5 The Chair calls for any of the following actions and documented in form 2.6 following a decision by the panel members based on voting:
- a. Approve – the standard and quality of the research protocol has adequate scientific merit which does not require any correction, with no major ethical concerns and only minimal spelling, grammar and syntax error.
 - b. Minor Modification (Member Secretary to Review/Primary Reviewer and/ or Informed Consent Reviewer to Re- Review) - reformatting, insertion of missing references, amendment of inaccurately cited references, improvement in spelling, grammar, and syntax errors.
 - c. Major Modification (require full board deliberation/Primary Reviewer and/ or Informed Consent Reviewer to Re- Review) - Revision of literature, improvement of declaration of objectives and statement, extensive revision of the entire study protocol such as improvement of methodology and statistical analysis.
 - d. Recommend to Disapprove- major ethical issues which affect the risk/ benefit ratio to the research participant.
- 2.5.5.6 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).
- 2.5.5.7 All revised study protocols should be submitted to the secretariat within **sixty (60) working days** from the date of letter/notification containing reviewer's comments. Researchers are allowed to request for extension in writing.

- 2.5.5.8 A reminder will be issued to the PI **fourteen (14) working days** before the correction due date via email.
- 2.5.5.9 As for resubmission of the corrected study protocol, the subsequent review by the primary reviewers shall be within **seven (7) working days** after the correction is made by the PI.
- 2.5.5.10 A memo of approval 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 via email within **seven (7) working days**.
- 2.5.5.11 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) working days**.

2.5.6 Discussion of post-approval submissions

Chair to present at the full board meeting matters that are classified as full board items. **The expedited review result will be submitted as a supplementary document during the full board meeting.**

2.5.7 Review of results of Expedited Review

- 2.5.7.1 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.
- 2.5.7.2 PASC makes decisions on all expeditable items but only recommends decisions on full board items.

2.5.8 Adjournment of the meeting

- 2.5.8.1 Before closing the meeting, the Chair calls for any non-study protocol matters that need attention or action, as the need arises.
- 2.5.8.2 Manual cross checking of attendance list with all attendees will be done regularly by the secretariat. Member secretary will make an announcement to all attendees to sign the attendance before the meeting ends.
- 2.5.8.3 With no further matters for discussion, the Chair formally adjourns the meeting, with the time noted by the Secretariat Staff.

2.5.9 Collection and storage or disposal of meeting materials

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

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

2.6 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

2.6.1 Preparation for Conduct of Special Meeting

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

2.6.1.2 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.

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

2.6.2 Conduct of Special Meeting

2.6.2.1 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.

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

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

2.6.3 Collection and storage or disposal of meeting materials

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

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