

 	<p>JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA</p> <p>I. STRUCTURE & COMPOSITION</p>
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1.0 OBJECTIVES

This SOP describes the Terms of Reference (TOR) which provide the organizational framework for the structure and composition of the UPM Ethical Committee on Research involving Human (JKEUPM). This SOP also describes and provides the procedures, templates, and forms that are related to nomination, appointment, privacy and confidentiality, training, and honorarium.

2.0 SCOPE

This SOP applies to JKEUPM and the composition of review panels, including all the subcommittees (e.g. Post Approval Subcommittee (PASC), Lay Person Reviewer Subcommittee (LPRS)), within the JKEUPM, which will carry out the task of providing an independent review of research protocols involving human subjects that are submitted to the JKEUPM by members of the faculty, students, and employees of UPM. Protocols involving non-human living vertebrates are referred to the Institutional Animal Care and Use Committee (IACUC).

This SOP describes the general ethical basis or values on which the JKEUPM is based, the panel composition and appointment of JKEUPM personnel, and duties and responsibilities of JKEUPM personnel, including attendance, training, expected review deliverables, and disclosure of conflict of interest.

3.0 RESPONSIBILITIES

The JKEUPM was established under the authority of the Senate of Universiti Putra Malaysia on 8 September 2011. The Deputy Vice Chancellor (Research and Innovation) is responsible for appointing the JKEUPM Chair and Panel Members, and providing the terms of reference for these appointments in accordance with prevailing university policies, guidelines, and regulations.

It is the responsibility of JKEUPM Chair, Panel Members, all subcommittees members and Secretariat to study, comprehend and comply with, the procedures and guidelines set by JKEUPM.

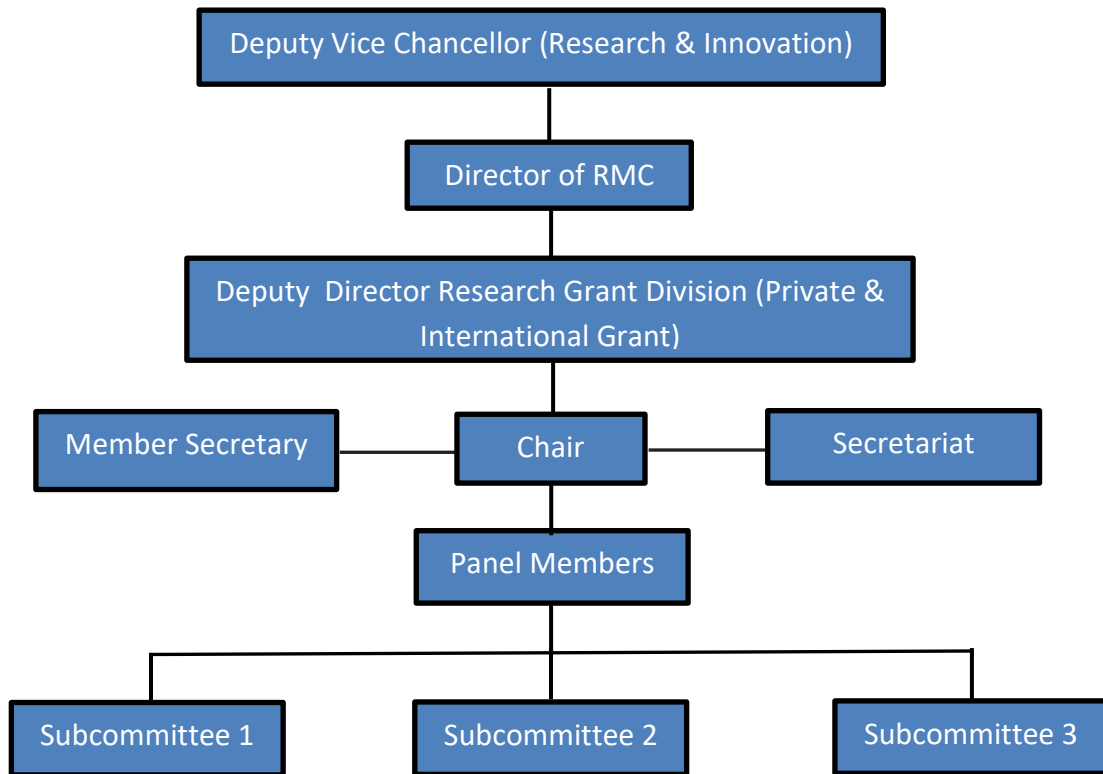
It is the responsibility of all newly appointed JKEUPM Panel Members and subcommittees members to read, understand, accept, and sign required appointment forms at the start of their appointment or reappointment to JKEUPM. If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in JKEUPM or to be disallowed in the deliberations of certain protocols.

It is the responsibility of new JKEUPM members to undergo training during the course of his appointment and existing JKEUPM members to continuously update themselves and train on relevant knowledge and skills. JKEUPM Chair shall enjoin JKEUPM members to attend trainings/ seminars/ workshops as needed, and ensure that adequate resources are provided for

continuing professional development. Therefore UPM is responsible for allocating an annual budget for specific trainings and other educational activities for JKEUPM members.

4.0 CONSTITUTION AND FUNCTIONS

4.1 Organizational Structure of the JKEUPM



4.2 JKEUPM Review Panels

- 4.2.1 **Review Panels** are tasked to perform institutional review and issue ethical clearance or ethical approval to study protocols submitted for its consideration.
- 4.2.2 The panel is composed of at least five appointed members including Chair.
- 4.2.3 The panel is composed of scientific and/ or medical members, and non-scientific members wherein at least **one (1)** independent member **AND** at least **one (1)** lay member are both present. Medical members refer to medical doctors.
- 4.2.4 The Panel Members should have various backgrounds and should have adequate representation of members with regard to religious background, ethnic groups and gender.
- 4.2.5 Members are selected according to their personal capacities; based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of JKEUPM.

- 4.2.6 Appointment is for a period of up to **three (3)** years for the Chair and Panel Members. Appointments may be renewed on the recommendation of the JKEUPM Chair and upon approval of the Deputy Vice Chancellor Research and Innovation) (DVC). Member Secretary and all subcommittee Chairs are appointed by JKEUPM Chair. **The JKEUPM Chair is the Dean of Faculty of Medicine and Health Sciences. The JKEUPM member secretary is the Deputy Dean (Research) of the Faculty of Medicine and Health Sciences.**
- 4.2.7 Members are expected to attend all Full Board meetings. Members will be disqualified and removed from the committee if they are absent for three (3) meetings without a valid reason. The DVC reserves the right to replace the disqualified member.
- 4.2.8 JKEUPM members work on behalf of the University and are indemnified by the University against all litigations and liabilities that may arise from the work carried out by the Committee.
- 4.2.9 Panel assignments should take into consideration the appropriate mix of senior and junior members.
- 4.2.10 Panel Members may be requested to participate in the meetings of other subcommittees, upon recommendation of the JKEUPM Chair.
- 4.2.11 JKEUPM may further be supported in its deliberation on specific protocols or requests for advice on specific ethical and/ or technical issues by Independent Consultant.

4.3 JKEUPM Post Approval Subcommittee (PASC)

- 4.3.1 The purpose of PASC is to provide direction in relation to the process of post approval submissions for the study protocol or study protocol- related documents. The description of the process includes the submission procedures, required forms, and documentation of committee action, communication of committee action with the Principal Investigators (PI) and filing of the results.
- 4.3.2 Appointed members from JKEUPM include at least **five (5)** members (including chair) whose primary area of expertise is in scientific area (Scientific Person) and **two (2)** members whose primary area of expertise is in non-scientific area (Layperson).
- 4.3.3 PASC is accountable for reviewing all submissions of the study protocol and study protocol-related documents after approval has been issued and decide on them accordingly. The submissions include:
- a. requests for amendments
 - b. continuing review applications
 - c. final reports
 - d. non-compliance (deviation or violation) reports

- e. early study termination
- f. queries from stakeholders
- g. serious adverse event (SAEs) reports
- h. suspected unexpected serious adverse reactions reports (SUSARs)
- i. site visit reports.

4.3.4 The membership of PASC will commit to:

- a. attend all scheduled meetings
- b. share all communications and information across members
- c. make timely decisions and take action on the given responsibility
- d. assess the urgency of the amendment approval and act accordingly
- e. be alerted to potential issues that may rise during the process of reviewing submissions

4.3.5 All meetings will be chaired by the Chair of PASC. Chair may appoint a member of PASC to chair the meeting in his/her absence. A meeting quorum will consist of at least **two (2)** of Scientific Persons (including chair) and **one (1)** Layperson. Decision is made by consensus. In the absence of consensus, the matter will be brought up to the main committee for the decision.

4.3.6 Meetings will be held monthly i.e. **two (2)** weeks before the JKEUPM meeting. Meeting's agenda minutes will be provided by the secretariat. If required, subgroups meetings will be arranged outside of the scheduled meeting time. All issues or decisions made in the meeting should be reported and endorsed at JKEUPM meeting.

4.4 Lay Person Reviewer Subcommittee

4.4.1 The purpose of LPRS is to review research proposals involving human subjects to bring a societal perspective to the issues under discussion to ensure human subject protection and safety. LPRS evaluates benefits and risks to human subjects and reviews protocols to ensure that language and other aspects of a study make sense to the layperson.

4.4.2 Appointed members should consist of at least **five (5)** members (including chair who is the panel member of the JKEUPM). Members are appointed upon recommendation of the LPRS Chair and approved by the Chair of JKEUPM.

4.4.3 LPRS is accountable for reviewing all submissions of the study protocol and study protocol-related documents submitted to them and decide on them accordingly for the purpose of protecting the rights and safety of the research participants from the layperson's perspective. The submissions include:

- a. Research Proposal
- b. Questionnaire, Interview questions (if any)
- c. Respondent's Information Sheet and Consent
- d. Respondent's Information Sheet and Guardian's/Parent's Consent

- e. Evidence of approval from institution(s) to conduct study

4.4.4 The membership of LPRS will commit to:

- a. Attend all scheduled meetings
- b. Make timely decision and take action on the given responsibility
- c. Assess the urgency of submissions and act accordingly
- d. Be alerted to potential issues that may rise during the process of reviewing submissions to the committee

4.4.5 All meetings will be chaired by the Chair of LPRS. Chair may appoint a member of LPRS to chair the meeting in his/her absence. A meeting quorum will consist of at least **three (3)** persons (including chair). Decision is made by consensus. In the absence of consensus, the matter will be brought up to the main committee for the decision.

4.4.6 Meetings will be held monthly before the JKEUPM meeting. Meeting's agenda minutes will be provided by the secretariat. If required, subgroups meetings will be arranged outside of the scheduled meeting time. All issues or decisions made in the meeting should be reported and endorsed at JKEUPM meeting.

4.5 Resignation, disqualification, and replacement of members

4.5.1 A member may resign his/ her position by submitting a letter of resignation to the DVC through the JKEUPM Chair.

4.5.2 A member may not be reappointed for non-compliance of duties and responsibilities stated herein.

4.5.3 A member who has resigned and members who will not be re-appointed will be replaced by new members upon recommendation of the JKEUPM Chair and approval of the UPM DVC.

4.6 General Duties and Responsibilities of JKEUPM Members

4.6.1 JKEUPM Review Panel members should submit their updated curriculum vitae which will be filed at the JKEUPM Membership File (contains CV, Terms of Appointment, and copies of Training Certificates of each member).

4.6.2 Members are required to sign **JKEUPM FORM 1.1: LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to JKEUPM in the course of its work.

4.6.3 Members should be willing to publicise their full name, profession, and affiliation to JKEUPM upon request.

- 4.6.4 Members must commit to record all financial relationships, and any conflict of interest within or related to JKEUPM and make them available upon request.

4.6 Specific Duties and Functions of JKEUPM Members

4.6.1 JKEUPM Chair

- a. Chair the full board meeting
- b. Propose membership
- c. Recommend policy amendments and changes
- d. Represent UPM in national and international ethics forums
- e. Oversee the operations of the JKEUPM panels and other subcommittees
- f. Supervise the management of the JKEUPM Office
- g. Act on suggestions, complaints, and queries from stakeholders

4.6.2 JKEUPM Member Secretary

- a. Ensure JKEUPM compliance with international, national, and institutional policies governing human subject research and human subject protections
- b. Recommend updates in JKEUPM policies and procedures in accordance with emerging national and international policy trends
- c. Prepare new JKEUPM documents as needed
- d. Maintain and update JKEUPM manual of policies and standard operating procedures
- e. Supervise the issuance of all JKEUPM communications in respect of JKEUPM panel decisions and actions
- f. Recommend the development, implementation, and monitoring of JKEUPM policies and procedures to the JKEUPM Chair
- g. Manage the JKEUPM office under the supervision of the JKEUPM Chair
- h. Ensure the basic training, orientation, and continuing education of JKEUPM review panel members and staff
- i. Inform research investigators regarding JKEUPM application processes.
- j. Liaise with stakeholders outside UPM
- k. Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the JKEUPM review panel members
- l. Perform other JKEUPM-related tasks that may be assigned to him/her by the JKEUPM Chair

4.6.3 JKEUPM Panel Member

- a. The role of the scientific and/or medical member is to focus on the review of the study protocol, while the role of the non-scientific or layperson is to focus on the review of the informed consent process and form.
- b. The roles of the affiliated and independent members in terms of the review are similar, however, the independent member is expected to

provide an external perspective to ensure the independence of the position of the JKEUPM.

- c. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation.
- d. Familiarize him/herself with the SOPs of the JKEUPM, his/her terms of reference, and the international and national guidelines on research ethics.
- e. Participate in initial review (initial submission and resubmission)
- f. Participate in Site Visits and similar activities as needed.
- g. Maintain confidentiality of the documents and deliberations of JKEUPM meetings.
- h. Declare any conflict of interest in general and for specific protocols for review.
- i. Participate in required training with proof of attendance in such training activity submitted to the secretariat.
- j. Refer to the JKEUPM Chair for any suggestion, complain, or grievance of research participants, principal investigators, and/or sponsors before acting on them and after consulting Panel Members.
- k. Do other JKEUPM-related duties that may be requested of him/her by the JKEUPM Chair or respective Panel Chair.

4.6.4 PASC Chair

- a. Preside over PASC Subcommittee meetings.
- b. Liaise directly with other JKEUPM personnel.
- c. Invite Independent Consultants to provide special expertise for specific serious adverse events reports.
- d. Perform other JKEUPM-related tasks that may be assigned to him/her by the DVC or JKEUPM Chair.

4.6.5 PASC Secretary

- a. Oversee preparation and accuracy of the agenda and minutes of the meeting.
- b. Supervise the preparation of communications pertinent to PASC-review-related actions to the Panel.
- c. Perform other PASC -related tasks that may be assigned to him/her by the PASC Chair.

4.6.6 PASC Members

- a. Familiarize him/herself with the JKEUPM SOP on Post-Approval Review and his/her terms of reference.
- b. Participate actively in the PASC meetings.
- c. Recommend appropriate action on PASC reports.
- d. Participate in Site Visits and similar activities as needed.
- e. Maintain confidentiality of the documents and deliberations of PASC meetings.

- f. Declare any conflict of interest in general and for specific protocols for review.
- g. Do other PASC -related duties that may be requested of him/her by the PASC Chair.

4.6.7 JKEUPM Administrative Secretariat Staff

- a. Ensure the proper management of JKEUPM Databases.
- b. Generate statistical data and other related information.
- c. Prepare and finalize related reports.
- d. Manage protocol submissions.
- e. Organize an effective and efficient tracking procedure for each protocol received.
- f. Prepare and distribute protocol files for review.
- g. Maintain the JKEUPM Active Files and Archives, References and other document files, especially their security and confidentiality
- h. Organize JKEUPM meetings.
- i. Prepare and maintain meeting agenda and minutes.
- j. Inform JKEUPM review panel members and personnel about training workshops and arrange for the latter’s participation in such workshops.
- k. Organize the preparation, review, revision, and distribution of SOPs and Guidelines.
- l. Provide the necessary secretariat support for JKEUPM related activities like Site Visits and communicating decisions to the PIs.
- m. Perform other related functions that may be assigned by the JKEUPM Chair.

4.7 Appointment of JKEUPM/ Regular Review Panel/ PASC Members/ Staff Workflow

Activity	Responsibility
Nominate JKEUPM Panel member ↓	JKEUPM Chair
Appoint Members ↓	Deputy Vice Chancellor (Research & Innovation)
File appointment documents	Secretariat Staff

Activity	Responsibility
Nominate JKEUPM PASC Chair/ PASC Members ↓	JKEUPM Chair
Appoint JKEUPM PASC Chair/ PASC Members ↓	JKEUPM Chair
File appointment documents	Secretariat Staff

5.0 TRAINING OF REGULAR JKEUPM REVIEW PANEL MEMBERS AND PERSONNEL

WORKFLOW

Activity	Responsibility
Set training requirements ↓	JKEUPM Chair
Find available training seminars, lectures, workshops ↓	Members/ Secretariat Staff
Signify intention to attend training or the JKEUPM Chair instructs member/s to attend ↓	Members/ Secretariat Staff
Attend training and keep the training record ↓	Members/ Secretariat Staff
Store and update training record in JKEUPM Membership Files under “JKEUPM panel members”	Secretariat Staff

5.1 Identification of required trainings, seminars, and workshops

5.1.1 The Chair periodically reviews compliance with training requirements for JKEUPM Chair, Panel Members, and Secretariat Staff.

5.1.2 The following are required courses:

- a. Basic Research Ethics
- b. Good Clinical Practice.
- b. JKEUPM Standard Operating Procedures.
- c. Continuing Ethics Education.
- d. Other ethics related educational activities on international trends including international specialists’ meetings organized for the exchange of experiences and information.

5.2 Search for available training activities

5.2.1 The Panel Member/ Secretariat Staff/ gets information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards, and various media channels and selects the ones most appropriate.

5.2.2 The JKEUPM Chair periodically reviews member training records and recommends the attendance to specific training activities or organizes training workshops.

5.2.3 In-house training provided by JKEUPM will be regularly included in the meeting agenda of the different panels and similarly documented in the **JKEUPM FORM 1.2: TRAINING RECORD.**

5.3 Storage & Filing

5.3.1 The Secretariat Staff fills out **JKEUPM FORM 1.2: TRAINING RECORD** to document the training/ workshop/ conference activities.

5.3.2 The Secretariat Staff files the training record in the JKEUPM Membership File.

6.0 SELECTION OF INDEPENDENT CONSULTANTS WORKFLOW

Activity	Responsibility
Invite Independent Consultants to the JKEUPM ↓	JKEUPM Chair
Sign JKEUPM FORM 1.1: LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS ↓	Independent Consultant
Appoint Independent Consultants ↓	UPM Deputy Vice Chancellor
Store record of Independent Consultants in the Independent Consultants File	Secretariat Staff

6.1 Invitation of Independent Consultants

6.1.1 The JKEUPM Chair determines the external expertise requirements based on need basis.

6.1.2 The JKEUPM Chair sends invitations to various professionals with specific scientific expertise to be part of the JKEUPM roster of Independent Consultants representing expertise not present in the current panels.

6.1.3 Similarly, in the course of protocol review, a JKEUPM Panel Member or the JKEUPM Chair may determine that a protocol should also be reviewed by an Independent Consultant.

6.1.4 The invitation includes the responsibilities and functions of the Independent Consultant as follows:

- a. Accomplish the following forms when requested:
 - i. **JKEUPM FORM 1.1: LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS**
 - ii. **JKEUPM FORM 1.3: SERVICE AGREEMENT FOR INDEPENDENT CONSULTANTS**
- b. Review assigned protocols that concern his/her specialty using the **JKEUPM FORM 2.3: APPLICATION FORM.**

- c. Attend the JKEUPM panel meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the JKEUPM Secretariat Staff if unable to attend the meeting.
- d. Return all protocol-related materials to the JKEUPM Secretariat Staff after review.

6.2 Appointment of Independent Consultants

- 6.2.1 JKEUPM Chair recommends Independent Consultants who have been invited and confirmed invitation to the UPM DVC.
- 6.2.2 UPM DVC appoints the independent consultant.
- 6.2.3 The appointment is for **two (2)** years.
- 6.2.4 Appointment may be terminated by either resignation of the consultant, or by the UPM DVC.