


Standard Operating Procedures

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JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA)

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1. Objectives

This SOP describes the Terms of Reference (TOR) which provide the organizational framework for the structure and composition of the Jawatankuasa Etika Penyelidikan Manusia (JEPeM) Universiti Sains Malaysia (English: Human Research Ethics Committee, Universiti Sains Malaysia (JEPeM-USM)). This SOP also describes and provides the procedures, templates, and forms that are related to nomination, appointment, privacy and confidentiality, training, and compensation of the committee members and associated members (subcommittee members and independent reviewers)

2. Scope

This SOP applies to the constitution of the JEPeM-USM and the composition of review panels, including all the subcommittees within the JEPeM-USM, which will carry out the task of providing an independent review of research protocols involving human participants that are submitted to the JEPeM-USM by members of the faculty, students, hospital staff, residents, fellows and other trainees and employees of the Universiti Sains Malaysia (USM), and non-USM principal investigators (PIs). The duty of JEPeM includes, but not limited to:

- a. Approve, modify or disapprove studies based upon consideration of protection of human participant (protection aspects)
- b. Require progress reports from the investigators and oversee the conduct of the study
- c. Suspend or terminate approval.

For protocols involving non-human living vertebrates are referred to the Animal Ethics Committee USM (AEC-USM).

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

3. Responsibilities

It is the responsibility of the USM Vice Chancellor to constitute and establish the JEPeM-USM. The Vice Chancellor is also responsible for appointing the JEPeM-USM Chair, Deputy Chairs, Advisors, Members, and Secretariat Staff; and providing the terms of reference for these appointments in accordance with prevailing university policies, guidelines, and regulations.

It is the responsibility of the JEPeM-USM Chair, Members, and all its subcommittees and Secretariat Staff to study, comprehend, comply with, and respect the procedures and guidelines set by the JEPeM-USM as approved by appropriate university officials. It is the responsibility of all newly appointed JEPeM-USM Members to read, understand, accept, and sign required appointment forms at the start of their appointment or reappointment to the JEPeM-USM. If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in the JEPeM-USM or to be disallowed in the deliberations of certain protocols.

It is the responsibility of new JEPeM-USM secretariat to undergo training during the course of his appointment and existing JEPeM-USM secretariat to continuously update themselves and train on relevant knowledge and skills. The JEPeM-USM Chair shall enjoin JEPeM-USM secretariat to attend

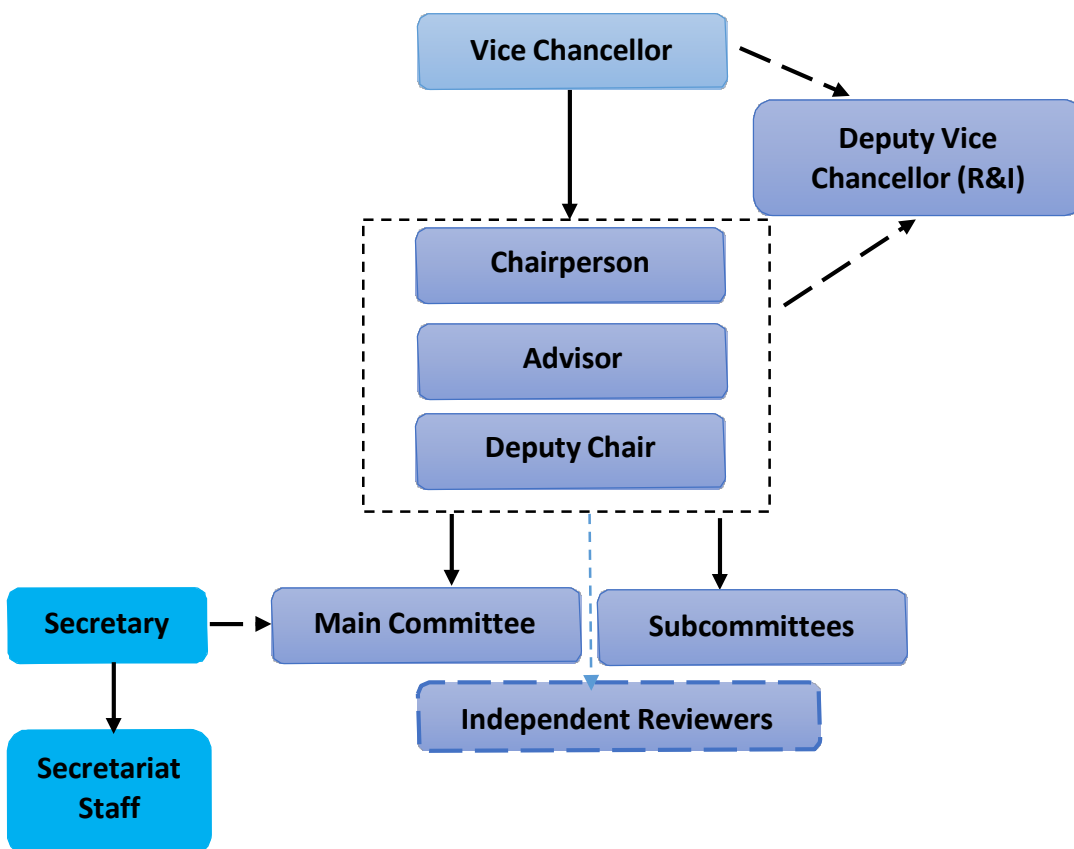
trainings/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore, USM is responsible for allocating an annual budget for specific trainings and other educational activities for JEPeM-USM secretariat.

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Malaysian Guideline for Good Clinical Practice (GCP), Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review. JEPeM USM is also responsible for notifying the National Pharmaceutical Control Bureau (NPCB) on any amendment(s)/updating any information within 30 working days if any of the following information is changed:

- a. JEPeM USM's contact or chairperson information which includes name, address, contact number and email address.
- b. Any change of membership, composition of the JEPeM USM.
- c. The JEPeM USM decision to discontinue reviewing of drug related clinical research.

4. Constitution and Functions

4.1 Organizational Structure of the JEPeM-USM



- 4.1.1 The Vice Chancellor appoints the Deputy Vice Chancellor of Research and Innovation to facilitate the discharge of functions of the JEPeM-USM along the line of authority indicated by the following chart.
- 4.1.2 The JEPeM-USM is established by authorization of the USM Vice Chancellor and exercises its mandate through the following structure:
- The USM Vice Chancellor, as the appointing officer
 - The Deputy Vice Chancellor for Research and Innovation, as the recommending officer
 - The JEPeM-USM, as the implementing office
- 4.1.3 Only the Vice Chancellor has the authority to dissolve the JEPeM-USM after due process.

4.2 Composition of JEPeM-USM Panels

- 4.2.1 The JEPeM-USM is composed of the following members:
- i. Chair
 - ii. Deputy Chair
 - iii. Director/Senior Representative of Hospital Universiti Sains Malaysia.
 - iv. Director/Senior Representative of Hospital Raja Perempuan Zainab II, Kota Bharu.
 - v. Clinical and non-clinical life scientist
 - vi. Social/Behavioral Scientist
 - vii. Research scientist
 - viii. Statistician
 - ix. Non-Institutional Members
 - x. Female Member (**at least one if not represented in any of the above group**)
 - xi. Member Secretary

The JEPeM-USM strive for equal representation of male and female members

- 4.2.2 The JEPeM-USM can recommend the appointment of new member(s) as and when the need arises.
- 4.2.3 There are Subpanel of this committee which is based in Health Campus and Main Campus. (Refer to List of JEPeM-USM Members). Subpanels is created according to the need of the campuses in term of number of proposals.
- 4.2.4 Members should be willing to publicize his/her full name, profession, and affiliation. Committee members will be required to sign a confidentiality agreement.
- 4.2.5 Members who are not staff of Universiti Sains Malaysia shall be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined from time to time by the Deputy Vice Chancellor, Research and Innovation, USM.

- 4.2.6 The quorum for the full board meeting is seven (7) members including at least one (1) member whose primary area of expertise is in a non-clinical area and/or at least one member who is other member of general public (non-institutional member) and 1 male/female member representation.
- 4.27 The committee shall comprise of both genders.
- 4.2.8 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 JEPeM-USM.
- 4.2.9 The duration of the membership will be three (3) years or less than three (3) years when and if necessary. Appointments may be renewed on the recommendation of the JEPeM-USM Chairperson and Deputy Vice Chancellor, Research and Innovation and upon approval of the Vice Chancellor.
- 4.2.10 The members of the Committee shall be re-appointed by the Vice-Chancellor of USM for a term of three (3) years or less than three (3) years. The selection of members will take into account the continuity and introduction of new members.
- 4.2.11 The JEPeM-USM may further be supported in its deliberation on specific protocols or requests for advice on specific ethical and/or technical issues by Independent Consultants (see JEPeM-USM SOP I - 5. SELECTION OF INDEPENDENT CONSULTANTS).

4.3 Composition of Serious Adverse Events (SAE) Subcommittee

- 4.3.1 The JEPeM-USM has a Serious Adverse Events (SAE) Subcommittee that will review all types of serious adverse events and recommend decisions to the full board meeting of JEPeM-USM.
- 4.3.2 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 JEPeM-USM.
- 4.3.3 The duration of the membership will be three (3) years or less than three (3) years when and if necessary. Appointments may be renewed on the recommendation of the JEPeM-USM Chairperson and Deputy Vice Chancellor, Research and Innovation and upon approval of the Vice Chancellor.

- 4.3.4 The members of the Committee shall be re-appointed by the Vice-Chancellor of USM for a term of three (3) years or less than three (3) years. The selection of members will take into account the continuity and introduction of new members.

4.4 Composition of Site Visit (SV) Subcommittee

- 4.4.1 The JEPeM-USM has the Site Visit Subcommittee that will review/evaluate and visit the selected researcher(s) and the study sites for the given project/related project involving risks to participants and generate recommendations for action of respective panel/s.
- 4.4.2 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 JEPeM-USM.
- 4.4.3 The duration of the membership will be three (3) years or less than three (3) years when and if necessary. Appointments may be renewed on the recommendation of the JEPeM-USM Chairperson and Deputy Vice Chancellor, Research and Innovation and upon approval of the Vice Chancellor.
- 4.4.4 The members of the Committee shall be re-appointed by the Vice-Chancellor of USM for a term of three (3) years or less than three (3) years. The selection of members will take into account the continuity and introduction of new members.

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 Vice Chancellor through the JEPeM-USM Chair.
- 4.5.2 A member may not be reappointed for non-compliance of duties and responsibilities stated here in.
- 4.5.3 A member who has resigned and members who are not to be re-appointed will be replaced by new members upon recommendation of the JEPeM-USM Chair and Deputy Vice Chancellor, Research and Innovation and approval of the USM Vice Chancellor.
- 4.5.4 Duration of appointment, disqualification, resignation, and replacement of administrative staffs are decided by the Vice Chancellor based on discussion with the Deputy Vice Chancellor, Research and Innovation and the Chairperson.

4.6 General Duties and Responsibilities of JEPeM-USM Members and Staff

- 4.6.1 JEPeM-USM members and secretariat should submit their properly signed and updated **CURRICULUM VITAE [JEPeM-USM FORM 1(B)]**, which will be filed at the JEPeM-USM Membership File (contains CV, Terms of Appointment, and copies of Training Certificates of each member).
- 4.6.2 Members are required to sign **JEPeM-USM FORM 1(C): CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the JEPeM-USM in the course of its work.
- 4.6.3 Members should be willing to publicize their full name, profession, and affiliation to the JEPeM-USM upon request.
- 4.6.4 Members must commit to record and make available upon request, all financial relationships, and any conflict of interest within or related to the JEPeM-USM.

4.7 General attributes of JEPeM-USM and Sub-committee members

- 4.7.1 Consist of different race, gender and cultural and educational background
- 4.7.2 Possess a comprehensive knowledge of national and international research ethics and regulation, institutional policies and relevant legislation.
- 4.7.3 Respecting diverse backgrounds, perspectives and sources of expertise, in particular the contributions of general public representative
- 4.7.4 Ability to function as a team particularly under stressful circumstances

- 4.7.5 Advocating and upholding the culture of integrity and respect within and outside the research community pertaining to the research ethics review process
- 4.7.6 Safeguarding rights and wellbeing of participants
- 4.7.7 Upholding JEPeM-USM decision that may not be popular with researchers, the research communities or University officials
- 4.7.8 Ready to pursue continues education in research ethics
- 4.7.9 Being honest and maintain confidentiality

4.8 Specific Duties and Functions of JEPeM-USM secretariat

4.8.1 JEPeM-USM Advisor

- 4.8.1.1 Recommends JEPeM-USM members
- 4.8.1.2 Recommends policy amendments and changes
- 4.8.1.3 Assist Chairs multi tasks, including chairing meetings, when the need arises
- 4.8.1.4 Represents JEPeM-USM in national and international ethics meetings and conferences
- 4.8.1.5 Liaises with stakeholders outside USM
- 4.8.1.6 Advice on administrative issues including but not limited to:
 - a. Membership
 - b. Standard Operation Procedure (SOP)
 - c. Filing / Archiving
 - d. Post Approval Process
- 4.8.1.7 Deal with queries and complaints

4.8.2 JEPeM-USM Chair

- 4.8.2.1 Recommends JEPeM-USM members
- 4.8.2.2 Recommends policy amendments and changes
- 4.8.2.3 Presides over meetings
- 4.8.2.4 Represents JEPeM-USM in national and international ethics forum

- 4.8.2.5 Liaises with stakeholders outside USM
- 4.8.2.6 Classify the review (full board, expedited or exempted) for initial protocol submissions.
- 4.8.2.7 Oversees the operations of the JEPeM-USM and all subcommittees
- 4.8.2.8 Supervises the management of the JEPeM-USM Office
- 4.8.2.9 Acts on suggestions, complaints, and queries from stakeholders
- 4.8.2.10 Plans and recommends basic training, orientation, and continuing education of JEPeM-USM members and staff to the university administration
- 4.8.2.11 Ensures JEPeM-USM compliance with international, national, and institutional policies governing human subject research
- 4.8.2.12 Ensures budget adequacy for JEPeM-USM operations and activities

4.8.3 **Deputy Chairs/Panel Chairs**

- 4.8.3.1 Deputy chair is also the panel chair. He/She shall chairs the assigned panel.
- 4.8.3.2 In case of unavailability, they can be replaced by another deputy chair.
- 4.8.3.2 Assume the responsibilities of the JEPeM-USM Chairperson as delegated in his/her absence.

4.8.4 **Member Secretary**

- 4.8.4.1 Oversee preparation and accuracy of the agenda of the meeting.
- 4.8.4.2 Supervise the preparation of the minutes of the meeting and approved the minutes of the meeting
- 4.8.4.3 Supervise the communication pertinent to protocol submission related actions to the researchers
- 4.8.4.4 Familiarize him/herself with the SOPs of the JEPeM-USM, his/her terms of reference, and the international and national guidelines on research ethics
- 4.8.4.5 Participate actively in the Full Board Review meetings and other JEPeM-USM meetings.
- 4.8.4.6 Supervise the management of the JEPeM-USM Office

- 4.8.4.7 Perform other JEPeM-USM related tasks that may be assigned to him/her by the JEPeM-USM Chairperson

4.8.5 Secretary

- 4.8.5.1 Prepares and issues the schedule of every JEPeM-USM meetings
- 4.8.5.2 Notifies Chair, committee members and Secretariat.
- 4.8.5.3 Prepares the meeting agenda and ensure all necessary documents are attached to the agenda
- 4.8.5.4 Makes prior review of the applications to ensure their completeness
- 4.8.5.5 Distributes the agenda and papers
- 4.8.5.6 Sends out invitation to Principal Investigator(s) notifying the date to attend the meeting at least five (5) working days in advance
- 4.8.5.7 Prepares the venue of the meetings
- 4.8.5.8 Takes minutes of the meeting
- 4.8.5.9 Is not eligible for voting or giving opinion in the meeting
- 4.8.5.10 Destroys the copies of the proposals which have been reviewed immediately after the meeting leaving the master copy for archiving
- 4.8.5.11 Ensures the minute of the meeting which is tabled is checked by the chairperson prior the next meeting.
- 4.8.5.12 Notifies applicants on decisions taken at the meeting and taking other follow-up action as necessary
- 4.8.5.13 Archives the meeting records

4.8.6 JEPeM-USM Members

- 4.8.6.1 Make a timely and thorough review and decision regarding protocols given to them for evaluation (See SOP II: PROTOCOL REVIEW for timelines)
- 4.8.6.2 Familiarize themselves with the SOPs of the JEPeM-USM, term of reference, and the international and national guidelines on research ethics
- 4.8.6.3 Participate actively in meetings of JEPeM-USM. In the event of multiple absences without valid reason, the member can be recommended to be

replaced.

- 4.8.6.4 Participate in decision making for appropriate action on recommendations based on monitoring reports from subcommittees
- 4.8.6.5 Participate in the review of the progress reports, final reports, and other amendments presented during the JEPeM-USM meeting
- 4.8.6.6 Maintain confidentiality of the documents and deliberations of JEPeM-USM meetings
- 4.8.6.7 Declare any conflict of interest in general and for specific protocols for review
- 4.8.6.8 Participate in required training with proof of attendances (examples: the use of new SOPs)
- 4.8.6.9 Submit an updated and signed CV at the start of each term of appointment
- 4.8.6.10 Refer to the JEPeM-USM Chair any suggestions, complaints, or grievances of research participants, PIs, and/or sponsors before acting on them and after consulting JEPeM-USM Members
- 4.8.6.11 Do other JEPeM-USM related duties that maybe requested of him/her by the JEPeM-USM Chair when necessary

4.8.7 Subcommittee Chair

- 4.8.7.1 Presides over subcommittee meetings
- 4.8.7.2 Liaises directly with other JEPeM-USM secretariat
- 4.8.7.3 Invites Independent Consultants to provide special expertise for specific situations
- 4.8.7.4 Performs other JEPeM-USM related tasks that may be assigned to him/her by the JEPeM-USM Chair

4.8.8 Subcommittee Members

- 4.8.8.1 Familiarize themselves with the JEPeM-USM SOP and term of reference
- 4.8.8.2 Participate actively in the Subcommittee meeting and activities.
- 4.8.8.3 Recommend appropriate action on the issues at hand

- 4.8.8.4 Maintain confidentiality of the documents and deliberations of Subcommittee Meetings
- 4.8.8.5 Declare any conflict of interest in general and for specific protocols review
- 4.8.8.6 Submit an updated and signed CV at the start of each term of appointment
- 4.8.8.7 Undertake other Subcommittee-related duties that maybe requested by the Subcommittee Chair

4.8.9 JEPeM-USM Secretariat Staff

- 4.8.9.1 Manage protocol submissions
- 4.8.9.2 Organize an effective and efficient tracking procedure for each protocol received
- 4.8.9.3 Prepare and distribute protocol files for primary review after discussion with the Chair
- 4.8.9.4 Maintain the JEPeM-USM Active File and Archives, **SUBMISSIONS LOG [JEPeM-USM FORM 4(M)]**, references and other document files, especially their security and confidentiality
- 4.8.9.5 Organize JEPeM-USM meetings (see SOP II-5: CONDUCT OF FULL BOARD MEETINGS)
- 4.8.9.6 Prepare and maintain meeting agenda and minutes
- 4.8.9.7 Facilitate, document and archive training for JEPeM-USM members and secretariat using the **JEPeM-USM FORM 1(D): TRAINING RECORD**
- 4.8.9.8 Organize the preparation, review, revision, and distribution of SOPs and guidelines
- 4.8.9.9 Provide the necessary secretariat's support for JEPeM-USM-related activities
- 4.8.9.10 Perform other related functions that may be assigned by the JEPeM-USM Chair

5. Selection of Independent Reviewers

- 5.1 The JEPeM-USM Chair determines and invites the external experts based on protocols submitted for review.

- 5.2 The invitation includes the responsibilities and functions of the Independent Consultant as follows:
- 5.2.1 Accomplish the following forms when requested:
- **JEPeM-USM FORM 1(C): CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE**
- 5.2.2 Review assigned protocols that concern his/her specialty using the **JEPeM-USM FORM 2(C): STUDY PROTOCOL ASSESSMENT FORM** and **JEPeM-USM FORM 2(D): INFORMED CONSENT ASSESSMENT FORM**.
- 5.2.3 Submit review report and whenever possible to attend the JEPeM-USM panel meeting for the deliberations on said protocols
- 5.2.4 Return all protocol-related materials to the JEPeM-USM Secretariat Staff after review.
- 5.2.5 Submit an updated and signed CV upon appointment.
- 5.2.6 List of the appointed Independent Consultants is available (Appendix I).
- 5.2.7 Roster of Independent Consultants will be prepared as a need arises.

6. Training of the Members and Consultants

- 6.1 Identification of required trainings, seminars, and workshops.
- 6.1.1 The Chairperson periodically reviews compliance with training requirements for JEPeM-USM members, sub-committee members (SAE and Site Visit), Independent Consultants and Secretariat Staff.
- 6.1.2 The following are required courses:
- Basic Research Ethics Course & Good Clinical Practice
 - JEPeM-USM Standard Operating Procedures
 - Continuing Ethics Education
 - Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information
- 6.2 Search for available training activities
- 6.2.1. The Chairperson/Member Secretary/Secretary gets information about training courses, workshops, conferences, etc. which are periodically

announced on websites, bulletin boards, email and various media channels and selects the ones most appropriate.

6.2.2. The Chairperson periodically reviews member training records and recommends the attendance to specific training activities or organizes training workshops.

6.2.3. In-house training provided by JEPeM-USM will be regularly conducted and documented in the **JEPeM-USM FORM 1(D): TRAINING RECORD**.

6.3 Attendance in training

6.3.1. The Member or Secretariat Staff attends the training and submits proof of attendance to the Coordinator, such as certificate of participation or completion and official receipt (for paid training courses).

6.3.2. The Secretary verifies validity of submitted documents.

6.3.3. Attendees are encouraged to echo their experience to the JEPeM-USM.

6.4 Storage & Filing

6.4.1. The Secretariat Staff fills out **JEPeM-USM FORM 1(D): TRAINING RECORD** to document the training/workshop/conference activities in chronological order.

6.4.2. The Secretariat Staff makes a copy of the form and files the copy in the JEPeM-USM Membership File.

7. Honorarium for Members and Consultants

7.1 The JEPeM-USM Chair initiates the recommendation of honorarium or increase thereof, either after a dialogue with JEPeM-USM members or with the Vice Chancellor.

7.2 Non-institutional members are compensated for attending meetings and other JEPeM-USM related-activities.

7.3 All members receive appreciation in terms of sponsorship to attend educational events regarding ethics in research or their subspecialty.

7.4 The recommendation will be submitted to the USM Vice Chancellor through the submission of the JEPeM-USM budget.

7.5 Approval of honorarium

7.5.1. The Vice Chancellor may approve or disapprove the recommendation.

7.5.2. Approval or disapproval will be indicated in the approval of the JEPeM-USM budget or amendment thereof.

7.6 Communication of honorarium information

7.6.1 The JEPeM-USM Members are informed of the honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations.

7.6.2 JEPeM-USM secretariat and Independent Consultants acknowledge the information upon receipt of notification.

Ahli Jawatankuasa Etika Penyelidikan Manusia USM (Dikemaskini 30th August 2022)*USM Human Research Ethics Committee Members (Updated 30th Ogos 2022)***Main Committee Members (Panel A) – Health Campus**

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| 6 | Prof. Habsah Hasan | PPSP/Microbiology & Parasitology |
| 7 | Assoc. Prof. Dr. Azizah Othman | PPSP/ Paediatric |
| 8 | Assoc. Prof. Dr. Salmi Abd Razak – Retired from USM | PPSP/ Paediatric |
| 9 | Dr. Mohamad Ikram Bin Ilias | PPSP/ Paediatric |
| 10 | Assoc. Prof Dr. Noraida Ramli | PPSP/ Paediatric |
| 11 | Dr. Mohd Rizal Mohd Zain | PPSP/ Paediatric |
| 12 | Dr. Ahmad Fuad Abdul Rahim – Retired from USM | PPSP/ Medical Education |
| 13 | Dr. Nurhanis Syazni Roslan | PPSP/ Medical Education |
| 14 | Prof. Dr. Wan Hazabbah Wan Hitam | PPSP/Ophthalmology |
| 15 | Prof. Dato' Dr. Nik Hisamuddin Nik Ab. Rahman | PPSP/Emergency Medicine |
| 16 | Prof. Dr. Rosline Hassan | PPSP/ Haematology |
| 17 | Dr. Mohd Nazri Hassan | PPSP/ Haematology |
| 18 | Prof. Dr. Zahiruddin Othman | PPSP/Psychiatry |
| 19 | Prof. Dato' Dr. Mafauzy Mohamed | PPSP/ Internal Medicine |
| 20 | Assoc. Prof. Dr. Wan Mohd Izani Wan Mohamed | PPSP/ Internal Medicine |
| 21 | Dr. Wong Mung Seong | PPSP/Internal Medicine |
| 22 | Prof. Dr. Aida Hanum Ghulam Rasool | PPSP/Pharmacology |
| 23 | Assoc. Prof. Dr. Azriani Berahim@Ab Rahman | PPSP/Community Medicine |

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| 24 | Prof. Dr. Aziah Daud | PPSP/Community Medicine |
| 25 | Assoc. Prof. Dr. Mohd Ismail Bin Ibrahim | PPSP/Community Medicine |
| 26 | Dr. Ahmad Filza Ismail | PPSP/Community Medicine |
| 27 | Dr. Zulkarnain Mustapha | PPSP/ Chemical Pathology |
| 28 | Dr. Ahmad Hadif Zaidin Samsudin | PPSP/Radiology |
| 29 | Dr. Chandran Nadarajan | PPSP/Radiology |
| 30 | Prof. Dr. Norsa'adah Bachok | PPSP/Biostatistics and Research Methodology |
| 31 | Assoc. Prof. Dr. Zaharah Sulaiman | PPSP/Women Health Development |
| 32 | Dr. Mohd Nizam Md Hashim | PPSP/Surgery |
| 33 | Dr. Wan Muhamad Mokhzani Wan Muhamad Mokhter | PPSP/Surgery |
| 34 | Dr. Nik Adilah Nik Othman | PPSP/ Otorhinolaryngology |
| 35 | Dr. Geshina Ayu Mat Saat | PPSK |
| 36 | Dr. Helmi Mohd Hadi Pritam | PPSK |
| 37 | Dr. Sabreena Binti Safuan | PPSK |
| 38 | Dr. Mohd Zulkifli Abdul Rahim | PPSK |
| 39 | Prof. Dr. Normastura Abd Rahman – Quit as IR | PPSG |
| 40 | Dr. Rabihah Alawi | PPSG |
| 41 | Dr. Siti Nurbaya Mohd Nawi | PPSP/Internal Medicine |
| 42 | Dr. Nurashikin Mohammad | PPSP/Internal Medicine |
| 43 | Assoc. Prof. Dr. Md. Salzihan Md. Salleh | PPSP/Pathology |
| 44 | Assoc. Prof. Dr. Sharifah Emilia Tuan Sharif | PPSP/Pathology |

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|----|---|--------------------------|
| 45 | Assoc. Prof. Dr Abdul Nawfar Sadagatullah | PPSP/Orthopaedic |
| 46 | Assoc. Prof. Dr Tengku Muzaffar Tengku Mohamad Shihabudin | PPSP/Orthopaedic |
| 47 | Assoc. Prof. Dr Ismail Munajat | PPSP/Orthopaedic |
| 48 | Prof. Dr. Irfan Mohamad | PPSP/Otorhinolaryngology |
| 49 | Dr. Ariffin Marzuki Mokhtar | PPSP/Anaesthesiology |
| 50 | Dr. Sharifah Zubaidiah Syed Jaapar | PPSP/Psychiatry |
| 51 | Dr. Norzila Zakaria | PPSP/Psychiatry |

List of Independent Reviewers – USM Main Campus

| No. | Name | Department/School |
|-----|--|--|
| 1 | Assoc. Prof. Dr. Elisha Nasruddin | Graduate School of Business |
| 2 | Dr. Fathyah Hashim | Graduate School of Business |
| 3 | Prof. Dr. Intan Hashimah Mohd Hashim | School of Social Sciences |
| 4 | Dr. Mohd Taufik Mohammad – Quit as IR: Effective on Oct 2022 | School of Social Sciences |
| 5 | Dr. Nurul Farhana Low Abdullah | School of Humanities |
| 6 | Dr. Saravanan P. Veeramuthu | School of Humanities |
| 7 | Prof. Dr. Noraida Endut | KANITA |
| 8 | Dr. Mohammad Tasyriq Che Omar | School of Distance Education |
| 9 | Dr. Diana Mohamad | School of Housing, Building and Planning |
| 10 | Dr. Muneera Esa | School of Housing, Building and Planning |
| 11 | Dr. Massoomeh Hedayati Marzbali | School of Housing, Building and Planning |
| 12 | Dr. Jestin Nordin | School of Housing, Building and Planning |
| 13 | Dr. Nurzali Ismail | School of Communication |
| 14 | Assoc. Prof. Dr. Shuhaida Md Noor | School of Communication |
| 15 | Assoc. Prof. Dr. Juliana Abdul Wahab | School of Communication |
| 17 | Dr. Johan Awang Othman | School of The Arts |
| 18 | Dr. Mohd Najib Abdullah Sani – Resign from USM | School of The Arts |
| 19 | Assoc. Prof. Dr. Hasliza Abdul Halim | School of Management |
| 20 | Assoc. Prof. Dr. Wong Wai Peng – Quit as IR | School of Management |
| 21 | Dr. Samah Ali Mohsen Mofreh | School of Educational Studies |

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| 22 | Prof. Dr. Lee Lay Wah - Retired | School of Educational Studies |
| 23 | Dr. Kimberly Kong Kim Lain | School of Educational Studies |
| 24 | Dr. Thien Lei Mee | School of Educational Studies |
| 25 | Dr. Siti Mastura Baharudin | School of Educational Studies |
| 26 | Assoc. Prof Dr. Aznan Che Ahmad | School of Educational Studies |
| 27 | Dr. Low Hui Min | School of Educational Studies |
| 28 | Dr. Rozniza Zaharudin | School of Educational Studies |
| 29 | Dr. Nurullizam Jamiat | Centre For Instructional Technology & Multimedia |
| 30 | Dr. Nik Noor Ashikin Nik Ab Razak | School of Physics |
| 31 | Dr. Nursakinah Suardi | School of Physics |
| 32 | Dr. Lee Lai Kuan | School of Industrial Technology |
| 33 | Dr. Mohd Najwadi Yusoff | School of Computer Sciences |
| 34 | Prof. Dr. Vicknasingam Balasingam Kasinather | CDR |
| 35 | Assoc. Prof. Dr. Zafarina Zainuddin | ABRC |
| 36 | Assoc. Prof. Dr. Md. Azman PKM Seeni Mohamed | AMDI |
| 37 | Dr. Rabiatul Basria Binti S.M.N.Mydin | AMDI |
| 38 | Assoc. Prof. Ir. Ts. Dr. Zuratul Ain Abdul Hamid | School Of Materials And Mineral Resources Engineering |
| 39 | Prof. Dr. Zaidi Mohd Ripin | School of Mechanical Engineering |
| 40 | Dr Siti Nasuha Hamzah | School of Biological Sciences |
| 41 | Dr. Nurul Izzah Shaari – Quit as IR | Advanced Medical and Dental Institute |
| 42 | Dr. Nurul Hashikin Ab Aziz | School of Physics |

<dd/mm/yyyy>

<TITLE, NAME>
DESIGNATION
ADDRESS

Dear <Title>:

I am pleased to inform you that you have been nominated to be a **CHAIR/DEPUTY CHAIR/MEMBER/SECRETARY/SECRETARIAT STAFF** of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM. The primary function of the JEPeM USM is to perform ethical review of research proposals and make appropriate recommendations to the researchers to ensure the safety of human participants recruited for the study.

If you accept this nomination, you will be appointed for a period of _____, starting from ___ to____, upon recommendation of the JEPeM-USM Chair and approval of the USM Vice Chancellor. The terms of reference of such appointment are as follows:

(INSERT FUNCTIONS AS APPROPRIATE)

SOP I-4.8.1 for Chair

SOP I-4.8.2 for Deputy Chair

SOP I-4.8.3 for Secretary

SOP I-4.8.4 for JEPeM-USM Members

SOP I-4.8.5 for Subcommittee Chair

SOP I-4.8.6 for Subcommittee Members

SOP I-4.8.7 for JEPeM-USM Secretariat Staff

If you have any questions regarding the information outlined in this letter of appointment, you may contact the JEPeM-USM Secretariat at 09-7672354/2362 for assistance.

Thank you and best regards.

Very truly yours,

<Title, Name> and Signature

Vice Chancellor of Universiti Sains Malaysia

Date: <dd/mm/yyyy>

<dd/mm/yyyy>

<Nama>

Jawatan

Alamat

Gelaran (Prof., Prof. Madya, Dr., Tuan/Puan/Encik/Cik):

PELANTIKAN SEBAGAI PENERUSI/TIMBALAN PENERUSI/AHLI/SETIAUSAHA/PENERUSI SUB JAWATANKUASA KECIL (SAE/SV)/AHLI SUB JAWATANKUASA KECIL (SAE/SV)/SEKRETARIAT JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA), UNIVERSITI SAINS MALAYSIA

Dengan segala hormatnya perkara di atas adalah dirujuk.

Bagi pihak Universiti, saya dengan hormatnya melantik tuan/puan sebagai **Pengerusi/Timbalan Pengerusi/Ahli/Setiausaha/Pengerusi Sub Jawatankuasa Kecil (SAE/SV)/Ahli Sub Jawatankuasa Kecil (SAE/SV)/Sekretariat**, Jawatankuasa Etika Penyelidikan (Manusia), Universiti Sains Malaysia berkuatkuasa mulai 1 Jun 2015 hingga 31 Mei 2018.

Untuk makluman pihak tuan, peranan utama Jawatankuasa Etika Penyelidikan (Manusia), Universiti Sains Malaysia adalah untuk menilai isu etika dalam penyelidikan serta mencadangkan tindakan yang sesuai kepada para penyelidik demi memastikan keselamatan, kebajikan dan juga kesejahteraan para peserta/pesakit yang terlibat dalam sesuatu kajian. Senarai tugas adalah seperti dalam Lampiran A (SOP I – 4.8.4 untuk Ahli JEPeM-USM). Senarai tugas adalah seperti dalam Lampiran A (SOP I – 4.8.1 untuk Pengerusi, SOP I – 4.8.2 untuk Timbalan Pengerusi, SOP I – 4.8.3 untuk Setiausaha, SOP I – 4.8.4 untuk Ahli JEPeM USM, 4.8.5 untuk Pengerusi Sub Jawatankuasa Kecil, 4.8.6 untuk Ahli Sub Jawatankuasa Kecil, 4.8.7 untuk Sekretariat).

Kesudian tuan/puan untuk menerima pelantikan ini amatlah dihargai dan diharap dapat memberi sumbangan untuk meningkatkan lagi kualiti penyelidikan di Universiti Sains Malaysia ke arah Universiti Penyelidikan bertaraf antarabangsa.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

‘Memastikan Kelestarian Hari Esok’

Yang benar,

Naib Canselor
Universiti Sains Malaysia

s.k Timbalan Naib Canselor (Penyelidikan & Inovasi)
Universiti Sains Malaysia

Curriculum Vitae

| | |
|---|------------------------------------|
| Name: | |
| Position: Date of Appointment: <dd/mm/yyyy> | Address: Contact No. E-mail: |
| 1. Education Background 1.1. Post-graduate degree 1.2. Graduate degree 1.3. Bachelor's degree 1.4. Other qualifications and specializations | |
| 2. Work Experience 2.1. Present Work Experience 2.2. Previous Work Experience | |

JEPeM-USM Member Signature

Date

<dd/mm/yyyy>

Confidentiality Agreement and Conflict of Interest Disclosure

Know all Individual by these Presents:

In view of the appointment of **<Title, Name>**, as a member of the Jawatankuasa Etika Penyelidikan (Manusia) USM (JEPeM-USM), and hereinafter referred to as the **Undersigned**, and whereas:

the **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines/

the **Undersigned** has been asked to assess adverse events reports occurring in research studies and protocols involving human participants in order to ensure that these events are addressed in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the **Undersigned** as a member/Subcommittee member of JEPeM-USM is based on individual merits and not as an advocate or representative of a home province/territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an JEPeM-USM member/Subcommittee member is to independently review both scientific and ethical aspects of research protocols involving human subjects/ adverse events occurring during the conduct of researches involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the JEPeM-USM must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

the following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed JEPeM-USM member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the JEPeM-USM to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the **Undersigned** in conjunction with and/or in the course of the performance of his/her duties as a member of the JEPeM-USM.

Any written information provided to the **Undersigned** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the JEPeM-USM.

As such, the **Undersigned** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the **Undersigned** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that her performance of this agreement is consistent with USM'S policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the JEPeM-USM to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the JEPeM-USM that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the JEPeM-USM.

The **Undersigned** will immediately disclose to the JEPeM-USM Chair any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Board, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that the JEPeM-USM member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the JEPeM-USM member(s) in question. The Board may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chair and may not participate in the JEPeM-USM review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[To the *Undersigned*: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the JEPeM-USM. A copy will be given to you for your records.]

In the course of my activities as a member of the JEPeM-USM, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chairperson upon termination of my functions as a Board member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

Noted:

<Title, Name> and Signature

JEPeM-USM CHAIR

Date: <dd/mm/yyyy>

<Title, Name> and Signature

Date: dd/mm/yyyy

Training Record

NAME:

| BASIC COURSES | | Training Provider | Venue | Date | USM Funded (Y/N) |
|----------------------|-------------------------------------|--------------------------|--------------|--------------|-------------------------|
| 1 | GCP Training | | | <dd/mm/yyyy> | |
| 2 | Research Ethics | | | <dd/mm/yyyy> | |
| 3 | Standard Operating Procedures (SOP) | | | <dd/mm/yyyy> | |

| CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures | | Training Provider | Venue | Date | USM Funded (Y/N) |
|--|--|--------------------------|--------------|--------------|-------------------------|
| 1 | | | | <dd/mm/yyyy> | |
| 2 | | | | <dd/mm/yyyy> | |
| 3 | | | | <dd/mm/yyyy> | |
| 4 | | | | <dd/mm/yyyy> | |
| 5 | | | | <dd/mm/yyyy> | |

| AS RESOURCE PERSON | Training Provider | Venue | Date | USM Funded (Y/N) |
|--------------------|-------------------|-------|--------------|------------------|
| 1 | | | <dd/mm/yyyy> | |
| 2 | | | <dd/mm/yyyy> | |
| 3 | | | <dd/mm/yyyy> | |

Certified Correct:

| | | |
|--------------------|-----------|-------|
| SECRETARY | Name | _____ |
| Date: | Signature | _____ |
| CHAIRPERSON | Name | _____ |
| Date: | Signature | _____ |

Training Request Form

| | |
|------------------------------------|--|
| Reference Number | |
| Name of Member | <Title, Name > |
| Date of Appointment | <dd/mm/yyyy> |
| Department/Institute as applicable | |
| Type of training requested | <input type="checkbox"/> Good Clinical Practice <input type="checkbox"/> Research Ethics <input type="checkbox"/> Standard Operating Procedures <input type="checkbox"/> Continuing Ethics Education <input type="checkbox"/> Other Educational Activities: _____ |
| Details of participation | <input type="checkbox"/> Participant only <input type="checkbox"/> Resource person <input type="checkbox"/> Others: _____ |
| Amount Requested | |
| Other sources of funding, if any | Amount: Source: |
| Signature | |
| Date | <dd/mm/yyyy> |

| | |
|-------------------|--|
| FIRST ENDORSEMENT | <p>I endorse the application of <Member> for the <training requested>. I certify that the supporting documents pertaining to the application are authentic and that <Member> has been an active member of the JEPeM-USM since <date of appointment>.</p> <p>_____ <Title, Name> and Signature Chairperson, Jawatankuasa Etika Penyelidikan (Manusia) USM Date: <dd/mm/yyyy></p> |
|-------------------|--|

| | |
|-----------------------|--|
| SECOND ENDORSEMENT | <p><Title, Name> and Signature _____ Deputy Vice Chancellor (Research & Innovation) Universiti Sains Malaysia Date: <dd/mm/yyyy></p> |
| THIRD ENDORSEMENT | <p><Title, Name> and Signature _____ Vice Chancellor, Universiti Sains Malaysia Date: <dd/mm/yyyy></p> |

<dd/mm/yyyy>

<TITLE, NAME >

DESIGNATION

ADDRESS

Dear <Title, Name>:

The **JEPeM-USM** is inviting you to be an Independent Consultant, in your capacity as a **(EXPERTISE)**, to provide expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which board has ascertained to require additional expert review.

The responsibilities of an Independent Consultant are as follows:

1. Submission or accomplishment of the following documents
 - a. Copy of **CURRICULUM VITAE [JEPeM-USM FORM 1(B)2019]**
 - b. Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE FORM [JEPeM-USM FORM 1(C)2019]**
2. Provision of the following consultation services
 - a. Completion of the **STUDY PROTOCOL ASSESSMENT FORM [JEPeM-USM FORM 2(C)2019]**
 - b. Completion of the **INFORMED CONSENT ASSESSMENT FORM [JEPeM FORM 2(D)2019]**
 - c. Attend the JEPeM USM panel meeting when invited where deliberations on said protocols will be made or alternatively, submit results of the review to the JEPeM USM Secretariat Staff if unable to attend the meeting.
 - d. Return all protocol-related materials to the JEPeM-USM Secretariat Staff after the review.
 - e. Submit an updated and signed CV annually.

If you agree to accommodate this request, please submit the documents indicated in **1.a** and **1.b** above, to facilitate processing of your appointment.

Thank you.

Very truly yours,

<Title, Name > and Signature

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

<dd/mm/yyyy>

<TITLE, NAME>
DESIGNATION
ADDRESS

Dear <Title>:

I am pleased to inform you that you have been terminated to be a **CHAIR/DEPUTY CHAIR/MEMBER/SECRETARY/SECRETARIAT STAFF** of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM due to the following reasons:

If you have any questions regarding this matter, you may contact the JEPeM-USM Secretariat at 09-7672354/2362 for assistance.

Thank you and best regards.

Very truly yours,

<Title, Name> and Signature

Vice Chancellor of Universiti Sains Malaysia

Date: <dd/mm/yyyy>

<dd/mm/yyyy>

<Nama>

Jawatan

Alamat

Gelaran (Prof., Prof. Madya, Dr., Tuan/Puan/Encik/Cik):

PENAMATAN LANTIKAN SEBAGAI PENERUSI/TIMBALAN PENERUSI/AHLI/SETIAUSAHA/PENERUSI
SUB JAWATANKUASA KECIL (SAE/SV)/AHLI SUB JAWATANKUASA KECIL (SAE/SV)/SEKRETARIAT
JAWATANKUASA ETIKA PENYELIDKAN (MANUSIA), UNIVERSITI SAINS MALAYSIA

Dengan segala hormatnya perkara di atas adalah dirujuk.

Bagi pihak Universiti, saya dengan dukacita menamatkan pelantikan tuan/puan sebagai **Pengerusi/Timbalan Pengerusi/Ahli/Setiausaha/Pengerusi Sub Jawatankuasa Kecil (SAE/SV)/Ahli Sub Jawatankuasa Kecil (SAE/SV)/Sekretariat, Jawatankuasa Etika Penyelidikan (Manusia), Universiti Sains Malaysia.**

Pertanyaan lanjut mengenai perkara ini sila hubungi pihak Sekretariat Jawatankuasa Etika Penyelidikan (Manusia) di talian 09-7672354/2352.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

‘Memastikan Kelestarian Hari Esok’

Yang benar,

Naib Canselor
Universiti Sains Malaysia

s.k Timbalan Naib Canselor (Penyelidikan & Inovasi)
Universiti Sains Malaysia