

Standard Operating Procedures

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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.

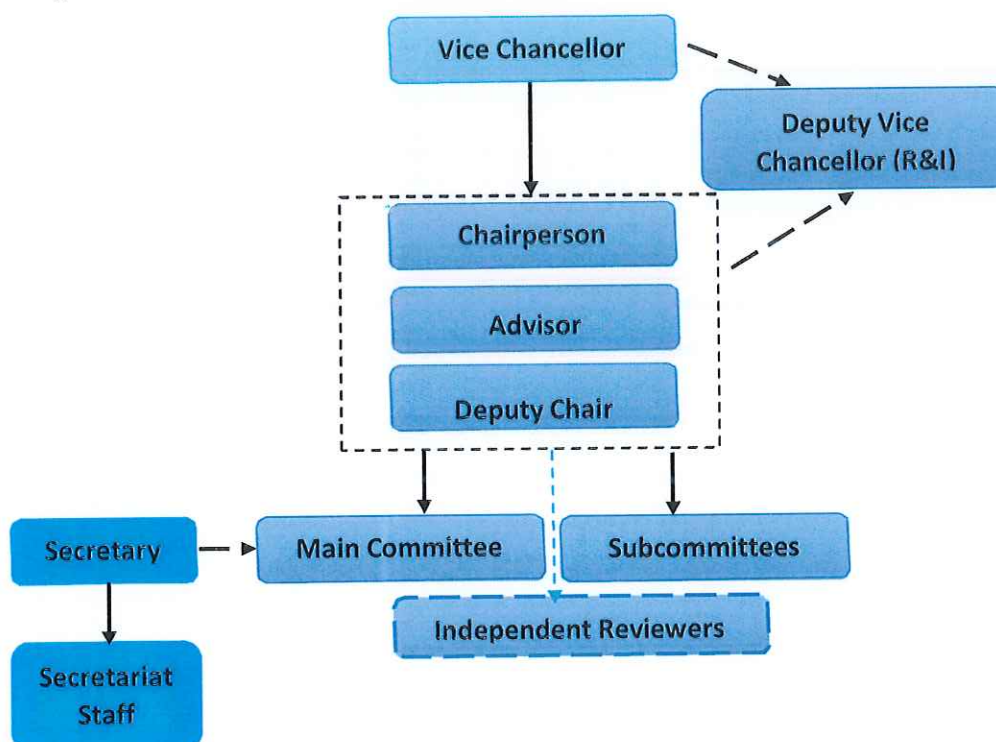
It is the responsibility of new JEPeM-USM secretariat to undergo training during the course of his appointment and existing JEPeM-USM secretariat to continuously update themselves and train on relevant knowledge and skills. The JEPeM-USM Chair shall enjoin JEPeM-USM secretariat to attend trainings/seminars/workshops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

- JEPeM USM's contact or chairperson information which includes name, address, contact number and email address.
- Any change of membership, composition of the JEPeM USM.
- 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 at least one (1) member who is other members of general public (non-institutional member) and 1 male/female member representation.
- 4.2.7 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 Confidentiality Agreement (CA) and Conflict of Interest (Col) Disclosure is submitted for every new appointment. Starting May 2024, prior to Vice Chancellor approval, candidates will need to sign Col and CA forms, and provide an updated Curriculum Vitae (CV). Completed CA, Col Disclosure forms and updated CV should be returned before formal appointment letter from the Vice Chancellor can be issued.
- 4.2.11 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.
- 4.2.12 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 If members resign in the middle of the term, it is their responsibility to inform Chairperson and they will at least provide electronic communication which will be forwarded to the VC.
- 4.5.2 JEPeM will only discontinue membership of non-performing/underperforming members at the time of renewal of membership. Decisions about non-performing/underperforming of members will be made by the Chair/panel chairs and will be based on review of attendance and quality of reviews before the decision to suggest re-appointment will be made at the beginning a new term.
- 4.5.3 JEPeM will only discontinue membership of non-performing members at the time of renewal of membership.
- 4.5.4 A member may not be reappointed for non-compliance of duties and responsibilities stated here in.
- 4.5.5 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.
- 4.5.6 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 Chair 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.
- 4.8.3.3 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, Pls, 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 (IR)

- 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 Reviewers 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 When there is need for urgent input from Independent Reviewers (IR) to review a specific component, the appointment letter can be signed by Chairperson after receiving the Col and CV document. The formal appointment letter will be issued by Vice Chancellor office.
 - 5.2.4 Submit review report and whenever possible to attend the JEPeM-USM panel meeting for the deliberations on said protocols.
 - 5.2.5 Return all protocol-related materials to the JEPeM-USM Secretariat Staff after review.
 - 5.2.6 Submit an updated and signed CV upon appointment.
 - 5.2.7 List of the appointed Independent Consultants is available (Appendix I).
 - 5.2.8 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.