Standard Operating Procedures

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA

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Prof. Dr. Normala Ibrahim, Prof. Dr. Johnson Stanslas, Assoc. Prof. Dr. Shamala Paramasivam, En Fahrul	9	29 August 2022	• Add cover page, document history and glossary.

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UPM UNIVERSITI PUTRA MALAYSIA	**JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA**
	1. STRUCTURE & COMPOSTION

1.1 INTRODUCTION

The Ethics Committee for Research Involving Human Subjects Universiti Putra Malaysia (Jawatankuasa Etika Universiti Penyelidikan Melibatkan Manusia) started as The Medical Research Ethics Committee. This committee included the Animal Ethics component in 1998. Recently, however, the Animal Ethics Committee has been made as an independent entity dealing only with animal care and use under the official name of IACUC (Institutional Animal Care and Use Committee).

JKEUPM is specifically given the task of protecting research participants, and to make researchers be responsible in ensuring that the basic principles regarding the use of human subjects are observed in their research. JKEUPM is guided in its stance and decisions by the principles expressed in the Declaration of Helsinki (2008). The Declaration, which was first developed by the World Medical Association (WMA) in 1964, was intended to outline a number of ethical principles that need to be adhered to when medical research involving human subjects is carried out. There are numerous principles listed in the Declaration, but it states above all that the well-being of the human subject of the research must take precedence over all other interests and regulations, including national and international regulatory requirements.

In addition to the Declaration, a number of provisions from the Nuremberg Code of 1946 which pertain to the gathering of information in social science fields have also been utilised in the present set of guidelines, particularly the emphasis on protecting a subject's privacy, accurately representing the aims of a particular study to a subject, and the necessity of safeguarding a subject's well-being by not deliberately placing him/her in situations that can be deemed compromising.

JKEUPM is also guided by the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). JKEUPM recognizes ethical clearance from other Ethics Committees, e.g. from the Ministry of Health and other universities, which are recognized by the National Pharmaceutical Control Bureau (BPFK), Ministry of Health Malaysia. Thus, a research project which has received ethical clearance from any of these other committees does not require a separate clearance from JKEUPM. However, if the research project involves either undergraduate or postgraduate students at any point, a JKEUPM ethical clearance is needed.

The JKEUPM seeks to fulfil the requirements for international assurances and is established and functions in accordance with Malaysian law and regulations.

1.2 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.

1.3 SCOPE

This SOP applies to JKEUPM and the composition of review panels, including all the subcommittees (e.g. Post Approval Subcommittee (PASC), 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.

1.4 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 1.1 (Letter of Undertaking For JKEUPM Committee Member) and form 1.4 (Non Disclosure of Confidential Information and Conflict of Interest) 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.

The JKEUPM has the authority to:

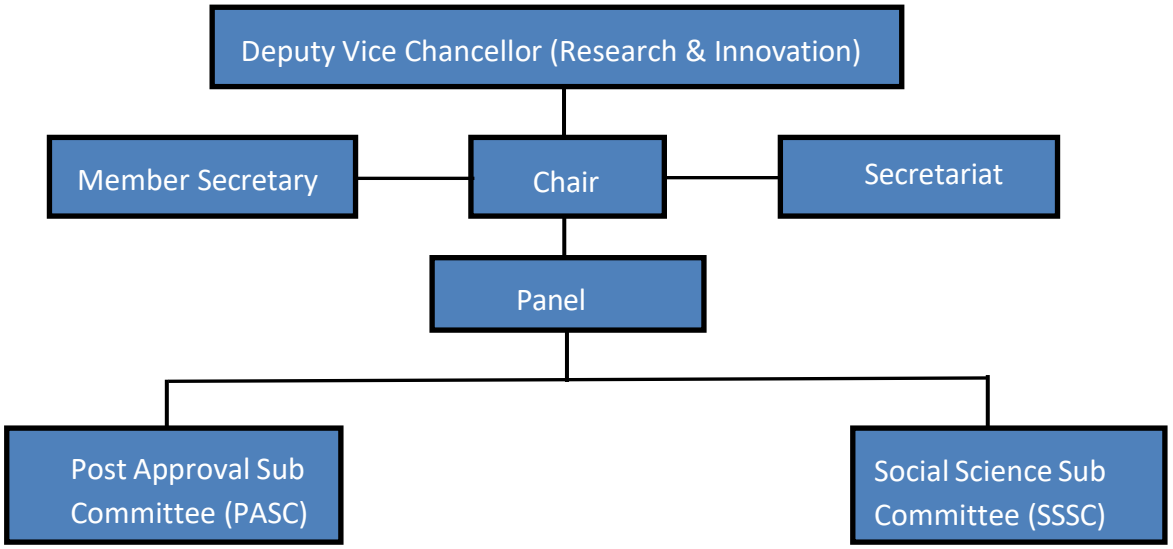
a) The authority to disapprove, modify or approve studies based upon consideration of human subject protection aspects.
b) The authority to require progress reports from the investigators and oversee the conduct of the study.

c) The authority to suspend or terminate approval of a study.

d) The authority to place restriction on a study.

1.5 CONSTITUTION AND FUNCTIONS

1.5.1 Organizational Structure of the JKEUPM



1.5.2 JKEUPM Review Panels

1.5.2.1 **Review Panels** are tasked to perform institutional review and issue ethical clearance or ethical approval to study protocols submitted for its consideration.

1.5.2.2 The panel is composed of at least five appointed members including Chair.

1.5.2.3 The panel is composed of scientific (medical/ non-medical, either affiliated or non-affiliated) members and layperson (member whose primary concern are in non-scientific areas, either affiliated or non-affiliated) wherein at least **one (1)** non-affiliated member **AND** at least **one (1)** layperson are both present. Medical members refer to medical doctors.

a. Scientific members:

Are expected to review assigned studies and contribute to the evaluation of a research project on its scientific merit, standard of practice and if the research project adequately protects the rights and welfare of subjects. They are either medical (medical doctors) or non-medical (health sciences, engineering, social sciences expertise and etc).

b. Layperson members:

Are members whose primary concerns are in non-scientific areas and expected to

provide inputs on matter relevant to their individual knowledge and expertise if research project adequately protects the rights and welfare of subjects

c. Non-affiliated members:

Are expected to provide input regarding their individual knowledge about the issues and research from their independent perspective relevant to their knowledge, expertise and experience, professional or otherwise. They are either scientific or lay person members

1.5.2.4 The Panel Members should have various backgrounds and should have adequate representation of members with regard to religious background, ethnic groups and gender.

1.5.2.5 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.

1.5.2.6 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 a senior medical member (preferably a Professor) who is established in own field of specialization and Member secretary is one of the panel members appointed upon approval of the DVC. The list of members will be updated when there is a change in JKEUPM membership. Any change of membership, composition of IEC, IEC contact or chairperson information which include IEC's name, address, chairperson's name, contact number and email address should be notified to NPRA accordingly. In addition, IEC decision to discontinue reviewing of drug related clinical research should be notified to NPRA.

1.5.2.7 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. Temporary termination of the appointment of the members will be done if they are taking sabbatical or study leave.

1.5.2.8 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.

1.5.2.9 Panel assignments should take into consideration the appropriate mix of senior and junior members.

1.5.2.10 Panel Members may be requested to participate in the meetings of other subcommittees, upon recommendation of the JKEUPM Chair.

1.5.2.11 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.

1.5.3 JKEUPM Post Approval Subcommittee (PASC)

1.5.3.1 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.

1.5.3.2 Appointed members should consist of at least **five (5)** members of JKEUPM. All members shall be scientific persons and layperson.

1.5.3.3 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.

1.5.3.4 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

1.5.3.5 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 four

(4) members. Decision is made by consensus. In the absence of consensus, the matter will be brought up to the main committee for the decision.

1.5.3.6 **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. Only full board items identified during the PASC meetings will be reported and endorsed at JKEUPM meetings.

1.5.4 JKEUPM Social Science Subcommittee (SSSC)

1.5.4.1 The purpose of SSSC is to review research proposals involving human subjects to ensure a research project has scientific merit, follows standard of practice and adequately protects the rights and welfare of subjects. SSSC reviews all research proposals that do not fall within the scope of health and medicine.

1.5.4.2 Appointed members should consist of at least five (5) members (including chair who is the panel member of the JKEUPM). All members shall be non-medical scientific persons

1.5.4.3 SSSC conducts scientific and ethical reviews of research that does not include the following:

a. Invasive physiological clinical and/or medical interventions
b. Research involving the use of human tissue
c. Human genetic research
d. Research involving staff, patients or resources of any hospital (both public and private).

These types of research should be reviewed by medical members of JKEUPM

1.5.4.4 The roles of the SSSC are to:

a. Ensure that the design and conduct of any human research that it reviews within the scope of its responsibilities conforms to the SOPs of the JKEUPM and other ethical standards to which the University has committed.
b. Ensure that rights and welfare of participants in any human research that it reviews within the scope of its responsibilities are adequately protected.
c. Advise the JKEUPM on ethical issues pertaining to any human research that it reviews within the scope of its responsibilities.

1.5.4.5 In fulfilling these roles, the membership of SSSC will commit to:

a. Review assigned studies and contribute to the evaluation of a study on its scientific merit, standard of practice and if the study adequately protects the rights and welfare of its subjects

b. Make a timely and thorough review and decision regarding study protocols given for evaluation
c. Be alerted to potential issues that may rise during the process of reviewing submissions
d. Alert SSSC regarding issues in protocols about which there is uncertainty
e. Familiarize with the SOPs of the JKEUPM, the terms of reference of the SSSC, and the international and national guidelines on research ethics.
f. Maintain confidentiality of the documents
g. Declare any conflict of interest in general and for specific protocols for review
h. Participate in required training with proof of attendance in such training activity submitted to the secretariat
i. Attend all scheduled meetings
j. Share all communications and information across members
k. Attend the Full Board meeting, if required.

1.5.4.6 All meetings will be chaired by the Chair of SSSC. Chair may appoint a member of SSSC to chair the meeting in his/her absence. A meeting quorum will consist of at least four (4) members. Decision is made by consensus. In the absence of consensus, the matter will be brought up to the main committee for the decision.

1.5.4.7 Meetings will be held quarterly. Meeting's agenda minutes will be provided by the secretariat. If required, subgroup meetings will be arranged outside of the scheduled meeting.

1.5.4.8 Only full board items identified during the PASC meetings will be reported and endorsed at JKEUPM meetings.

1.5.5 Resignation, disqualification, and replacement of members

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

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

1.5.5.3 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.

1.5.6 General Duties and Responsibilities of JKEUPM Members

1.5.6.1 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).

1.5.6.2 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.

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

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

1.5.7 Specific Duties and Functions of JKEUPM Members

1.5.7.1 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

1.5.7.2 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

1.5.7.3 JKEUPM Panel Member

a. The role of scientific members is to review assigned studies and contribute to the evaluation of a research project on its scientific merit, standard of practice and if the research project adequately protects the rights and welfare of subjects.
b. The role of layperson members (whose primary concerns are in non-scientific areas) is to provide inputs on matter relevant to their individual knowledge and expertise if research project adequately protects the rights and welfare of subjects
c. The role of non-affiliated members is to provide input regarding their individual knowledge about the issues and research from their independent perspective relevant to their knowledge, expertise and experience, professional or otherwise.
d. The panel members are expected to review the informed consent of a research protocol (informed consent reviewer). The medical members may review the informed consent of a non-medical research protocol and the non-medical members may review the informed consent of a medical research protocol. The layperson members may review informed consent of both medical and non-medical research protocols.
e. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation.
f. Familiarize him/herself with the SOPs of the JKEUPM, his/her terms of reference, and the international and national guidelines on research ethics.
g. Participate in the initial review either as a Primary Reviewer or informed Consent Reviewer (initial submission and resubmission).
h. Participate in Site Visits and similar activities as needed.
i. Maintain confidentiality of the documents and deliberations of JKEUPM meetings.
j. Declare any conflict of interest in general and for specific protocols for review.
k. Participate in required training with proof of attendance in such training activity submitted to the secretariat.
l. 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.
m. Do other JKEUPM-related duties that may be requested of him/her by the JKEUPM Chair or respective Panel Chair.

1.5.7.4 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.

1.5.7.5 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.

1.5.7.6 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.

1.5.7.7 SSSC Chair

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

1.5.7.8 SSSC Members

a. Familiarize him/herself with the JKEUPM SOP on Social Science Review and his/her terms of reference.
b. Participate actively in the SSSC meetings.
c. Recommend appropriate action on SSSC reports.
d. Participate in Site Visits and similar activities as needed.
e. Maintain confidentiality of the documents and deliberations of SSSC meetings.
f. Declare any conflict of interest in general and for specific protocols for review.
g. Do other SSSC -related duties that may be requested of him/her by the SSSC Chair.

1.5.7.9 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.

1.5.8 Appointment of JKEUPM/ Regular Review Panel/ PASC Members/ SSSC 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

Activity	Responsibility
Nominate JKEUPM SSSC Chair/ SSSC Members ↓	JKEUPM Chair

Appoint JKEUPM SSSC Chair/ SSSC Members ↓	JKEUPM Chair
File appointment documents	Secretariat Staff

1.5.9 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

1.5.10 Identification of required trainings, seminars, and workshops

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

1.5.10.2 The following are required courses:

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

1.5.11 Search for available training activities

1.5.11.1 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.

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

1.5.11.3 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.**

1.5.12 Storage & Filing

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

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

1.5.13 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

1.5.14 Invitation of Independent Consultants

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

1.5.14.2 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.

1.5.14.3 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.

1.5.14.4 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.

1.5.15 Appointment of Independent Consultants

1.5.15.1 JKEUPM Chair recommends Independent Consultants who have been invited and confirmed invitation to the UPM DVC.

1.5.15.2 UPM DVC appoints the independent consultant whose role is to provide independent scientific expertise and is not eligible to vote.

1.5.15.3 The appointment is for **two (2)** years.

1.5.15.4 Appointment may be terminated by either resignation of the consultant, or by the UPM DVC.

1.5.16 Appointment of Primary Reviewers

1.5.16.1 Primary reviewers of a research protocol can be either a panel members or an individual who have the area of expertise related to research protocol.

1.5.16.2 The term of reference include:

a. The role of scientific members is to review assigned studies and contribute to the evaluation of a research project on its scientific merit, standard of practice and if the research project adequately protects the rights and welfare of subjects.

b. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation.

c. Familiarize him/herself with the SOPs of the JKEUPM, his/her terms of reference, and the international and national guidelines on research ethics.

d. Maintain confidentiality of the documents

e. Declare any conflict of interest in general and for specific protocols for review.

f. Participate in required training with proof of attendance in such training activity submitted to the secretariat.

g. Attend the Full Board meeting if required.

1.5.16.3 Panel members recommends Primary Reviewers who have been invited and confirmed invitation to the JKEUPM Chair.

1.5.16.4 JKEUPM Chair appoints the Primary Reviewers who are non-panel members and they are not eligible to vote.

1.5.16.5 The appointment is for two (2) years.

1.5.16.6 Appointment may be terminated by either resignation of the individual or by the JKEUPM Chair.

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	2. PROTOCOL REVIEW

2.1 OBJECTIVES

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

2.2 SCOPE

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

2.3 RESPONSIBILITIES

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

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

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

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

2.4 INITIAL REVIEW WORKFLOW

2.4.1 Receipt and management of study protocol submission

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

2.4.1.2 The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist **within 2 days of receiving them**, and will sign/initial the document as evidence of acceptance.

2.4.1.3 Incomplete or incorrect submissions will not be accepted and will be returned to the Principal investigator (PI).

2.4.1.4 All clinical trials conducted locally must be registered with National Medical Research Registry (NMRR), including projects carried out at non Ministry of Health Malaysia facilities. All the registration numbers should be included in the JKEUPM application form before ethics approval being granted.

2.4.1.5 All research projects using Ministry of Health Malaysia facilities are required to obtain MREC approval. The approval needs to be submitted to the Deputy Dean of Research office of each faculty for its record keeping. This is to ensure that the office will be aware that its faculty staff has obtained ethics approval from IRB other than JKEUPM.

2.4.1.6 This includes all research projects using other institutions that have their own IRB. For research conducted in facilities other than UPM and **approved by the relevant ethics committees**, approval from JKEUPM is not necessary.

2.4.1.7 Approval from JKEUPM is not necessary for research conducted by UPM students abroad that has obtained ethical approval from the local IRB. However, JKEUPM will still accept submission from students to get ethical approval from JKEUPM to conduct a study abroad, in the event it becomes necessary.

2.4.2 Classification of submission

2.4.2.1 The JKEUPM Chair/Member Secretary classifies the study protocol review pathway as either Expedited Review or Full Board Review filtered through the following criteria for Expedited Review:

a. The research poses low risk.
b. The study does not involve vulnerable populations.
c. The study does not involve the collection of stigmatizing information.
d. The study uses anonymized or archived sample.
e. Protocols involving interviews/ questionnaires/ survey/group work/

conversations of a non-confidential nature not likely to be detrimental to the status or interests of subjects, and not likely to offend the sensibilitie s and sensitivities of subjects.

f. Those that involve collection of biological samples by non-invasive means (e.g., collection of body fluids or excreta, buccal or throat swab, collection of hair or nail clippings).
g. Collection data through non-invasive procedures (not involving general anaesthesia or sedation) routinely used in clinical practice and using medical devices approved by national regulatory authorities.
h. Research involving data, documents or specimens that have already been collected or will be collected for ongoing medical treatment or investigation.

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

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

2.4.2.3 The following study protocols are generally exempted from review:

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

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

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

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

2.4.3 Assignment of Primary Reviewers

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

2.4.3.2 The Secretariat Staff sends the study protocol to the primary reviewers once they are assigned.

2.4.4 Study Protocol Review

2.4.4.1 The Secretariat Staff sends study protocols to primary reviewers for full board and expedited review within **five (5) working days** after receipt of protocols.

2.4.4.2 Primary reviewers check for completeness of the documentation and information about the PIs, study sites and other documents required.

2.4.4.3 For both full board and expedited review study protocols, the primary reviewers return the reviewed protocols to the Secretariat Staff within **ten (10) working days** from receipt of protocols.

2.4.4.4 In the event the primary reviewers failed to meet the deadline, the secretariat will issue a reminder and give an extension of **seven (7) working days**. Failing which, the study protocol will be assigned to new primary reviewers, who will be given **seven (7) working days**.

2.4.4.5 Regular monitoring every **three (3) months** will be done by the Secretariat to monitor the timeline of the review process and the study protocol which does not meet above requirements will be assigned to new primary reviewers

2.4.4.6 For expedited review study protocols, the Secretariat Staff will notify the PI of the decision. For full board review protocols, PI will be notified of the decision after the meeting. The PI will have to revise the protocols according to the reviewer's suggestion.

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

a. RECOMMEND FOR APPROVAL (Full Board Review only)
b. APPROVAL (Applicable for Expedited Review only)
c. MINOR MODIFICATION (Member Secretary to Review/Primary Reviewer/ Informed Consent Reviewer to Re- review)
d. MAJOR MODIFICATION (require full board deliberation/Primary Reviewer/ Informed Consent Reviewer to Re- review)

e. RECOMMEND TO DISAPPROVE

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

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

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

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

2.4.4.11 The rejection letter will include information on:

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

2.4.5 Inquiry or Appeals of JKEUPM Decisions

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

2.5 FULL BOARD MEETING WORKFLOW

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

2.5.1 Regular meeting schedule

2.5.1.1 The JKEUPM Chair/ Member Secretary/Secretariat Staff must set its regular monthly meeting, e.g., “first Monday” of the month to facilitate preparations and regular attendance of Panel Members.

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

2.5.1.3 The Secretariat Staff ensures that the venue, equipment, and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment replacement or purchase of necessary supplies.

2.5.2 Distribution of the Meeting Agenda

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

2.5.3 Determination of quorum

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

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

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

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

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

2.5.4.2 The JKEUPM also allows, at the discretion of the Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe JKEUPM meetings. Non-members (who are not PIs) attending any JKEUPM Panel Meeting are required to sign a **JKEUPM FORM 1.4: NON DISCLOSURE OF CONFIDENTIAL INFORMATION AND CONFLICT OF INTEREST**

2.5.4.3 The Secretariat Staff documents the proceedings of the meeting under the supervision of the Member Secretary, as soon as the meeting is called to order by Chair, noting the time. The Secretariat Staff documents the development of the agenda, specifically all board opinions and action with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator.

2.5.4.4 The Chair calls upon the Member Secretary to formally confirm quorum by citing the attendance requirements.

2.5.4.5 The Chair calls for declaration of Conflict of Interest (COI) in respect of any study protocol or submission scheduled for review. Members declaring COI are documented by the Member Secretary. The Chair instructs the members who declared COI to recuse themselves from the deliberation of the respective study protocol for which the COI declaration was made.

2.5.4.6 The Chair presides over the review of the Minutes of the previous meeting. A declaration of motion for approval can be made by a member and then seconded by another member. The Chair then declares approval of the Minutes of the previous meeting.

2.5.4.7 The Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat Staff for inclusion in the Minutes of the current meeting.

2.5.4.8 Full board review of study protocol and study protocol-related submissions typically includes review of the following:

a. Study Protocol Submissions
   i. Resubmission or Study Protocols for Modification.
   ii. Clarificatory Interview.

2.5.4.9 The Chair may allow some modifications of the sequence of review in urgent circumstances. For example, if a clarificatory interview is included in the agenda, the panel may opt to move this up in the review sequence.

2.5.4.10 The Chair instructs the member who had previously declared conflict of (COI) to recuse himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such panel members may be called in by the panel to answer questions to assist in the board in arriving at a board action, but under no circumstances participate in the decision.

2.5.5 Discussion of initial study protocol submissions and resubmissions

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

2.5.5.2 The scientific primary reviewer is instructed to focus presentation of findings on scientific soundness and its impact on human subject protection, while the informed consent primary reviewer is instructed to focus presentation of findings on the informed consent process and informed consent form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies.

2.5.5.3 The Panel Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.

2.5.5.4 It is compulsory for the PI or other study team members to briefly explain their study protocols before the panel followed by question and answer session. Students are allowed to present the study protocols, however, the presence of their supervisor or co-supervisor is mandatory.

2.5.5.5 The Chair calls for any of the following actions and documented in form 2.6 following a decision by the panel members based on voting:

a. Approve – the standard and quality of the research protocol has adequate scientific merit which does not require any correction, with no major ethical concerns and only minimal spelling, grammar and syntax error.
b. Minor Modification (Member Secretary to Review/Primary Reviewer and/ or Informed Consent Reviewer to Re- Review) - reformatting, insertion of missing references, amendment of inaccurately cited references, improvement in spelling, grammar, and syntax errors.
c. Major Modification (require full board deliberation/Primary Reviewer and/ or Informed Consent Reviewer to Re- Review) - Revision of literature, improvement of declaration of objectives and statement, extensive revision of the entire study protocol such as improvement of methodology and statistical analysis.
d. Recommend to Disapprove- major ethical issues which affect the risk/ benefit ratio to the research participant.

2.5.5.6 JKEUPM allows investigators and other resource persons (such as an Independent Consultant commissioned by JKEUPM or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the panel meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the board).

2.5.5.7 All revised study protocols should be submitted to the secretariat within **sixty (60) working days** from the date of letter/notification containing reviewer's comments. Researchers are allowed to request for extension in writing.

2.5.5.8 A reminder will be issued to the PI **fourteen (14) working days** before the correction due date via email.

2.5.5.9 As for resubmission of the corrected study protocol, the subsequent review by the primary reviewers shall be within **seven (7) working days** after the correction is made by the PI.

2.5.5.10 A memo of approval for both full board and expedited reviews which identified the study protocol reference number, the documents reviewed and dates for the decision will be issued to the PI via email within **seven (7) working days**.

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

2.5.6 Discussion of post-approval submissions

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

2.5.7 Review of results of Expedited Review

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

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

2.5.8 Adjournment of the meeting

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

2.5.8.2 Manual cross checking of attendance list with all attendees will be done regularly by the secretariat. Member secretary will make an announcement to all attendees to sign the attendance before the meeting ends.

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

2.5.9 Colllection and storage or disposal of meeting materials

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

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

2.6 SPECIAL MEETINGS WORKFLOW

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

2.6.1 Preparation for Conduct of Special Meeting

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

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

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

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

2.6.2 Conduct of Special Meeting

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

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

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

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

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

2.6.3 Collection and storage or disposal of meeting materials

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

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

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3. POST APPROVAL

3.1 OBJECTIVES

This SOP describes how JKEUPM processes post approval submissions by the Principal Investigators (PI). The post approval subcommittee (PASC) will review all submissions and classify them to be processed either by expedited or full board review. PASC makes decisions on all expeditable items defined as requiring minor revisions such as addition and removal of team members, minor corrections in reports. PASC recommends decisions on full board items defined as major items that can affect the outcomes of the study such as change in objectives, methodology (like study site, study design, sampling, instruments), study title, and informed consent form. This chapter describes submission procedures, required forms, documentation of board action, communication of board action to the PI, and filing of results.

3.2 SCOPE

This SOP applies to all study protocol-related submissions after approval has been issued for the study protocol and study protocol-related documents. These submissions include requests for amendments (including ICF updates), continuing review applications, investigator's brochure (IB) updates, insurance updates, final reports, non-compliance (deviation or violation) reports, early study termination, queries from stakeholders, serious adverse event reports (SAEs) and suspected unexpected serious drug reactions (SUSARs), site visit reports, and other documents that are deemed relevant.

3.3 RESPONSIBILITIES

It is the responsibility of the PI to comply with post-approval review requirements, including the submission of required reports listed in JKEUPM approval letter.

The secretariat staff is responsible for receiving and processing all submissions, including inquiries or complaints from research participants and other stakeholders.

The secretariat performs periodic checks of all pending matters during the PASC Monitoring Meeting. The outcome will be discussed as one of the agenda of PASC monthly meeting.

When a site visit becomes necessary, it is the responsibility of the Chair to form a site visit team. The responsibilities of the assigned members are to conduct the site visit and issue a report for presentation in JKEUPM meeting. It is the responsibility of the secretariat staff to organize the site visit.

3.4 STUDY PROTOCOL AMENDMENTS, CONTINUING REVIEW APPLICATIONS, FINAL REPORTS, NONCOMPLIANCE REPORTS, EARLY STUDY TERMINATION APPLICATION, AND QUERIES, NOTIFICATIONS AND COMPLAINTS WORKFLOW

Activity	Responsibility
Receive and manage submission of documents (the secretariat staff checks the checklist for all the documents submitted and reviewed and verifies whether the documents were provided by the PI)	Secretariat Staff
Submit documents to the PASC Chair to determine classification of review as expedited or full board	Secretariat Staff
PASC reviews submissions classified as expedited review and makes a decision but only recommends decisions on full board items in PASC meeting; Primary reviewers may be invited to review submissions classified as full board items	PASC/Primary reviewers
Present full board items in JKEUPM meeting	PASC Chair
Communicate with PI	Secretariat Staff
Manage study protocol files	Secretariat Staff

*The whole process will take **sixty 60 working days**.

*Study participants can submit complaints to JKEUPM Secretariat at email address jkeupm@upm.edu.my

*Note: When complaints are received, they are brought to PASC monthly meeting and discussed. If it is a major issue, the PASC recommends its decision to the main board for further action.

3.4.1 Continuing Review Application

3.4.1.1 Ethical clearance or approval is granted for a period of one year. After approval, continuing review is required to be done at least once a year, depending on the risk assessment of the study protocol, and determined during initial review. This is facilitated through the submission of **JKEUPM FORM 3.1: PROGRESS REPORT.**

3.4.1.2 For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit **JKEUPM FORM 3.1: PROGRESS REPORT twenty one (21) working days** prior to expiry date.

3.4.1.3 The secretariat staff informs the respective PIs at least **thirty (30) working days** in advance of the due date of review.

3.4.1.4 All continuing review application packages will be sent to the PASC together with the originally approved protocol for approval.

3.4.1.5 All submissions will be reviewed and finalized by PASC at the following meeting.

3.4.1.6 PASC makes decisions on all expeditable items but only recommends decisions on full board items.

3.4.1.7 The secretariat staff places the study protocol continuing review application in the PASC report presentation at the next full board meeting.

3.4.1.8 PASC Chair to present continuing review application to JKEUPM members for deliberation.

3.4.1.9 The PI is notified of the JKEUPM decision noting which continuing review application are approved for use. The PI may be required to provide additional information, or submit additional documents. The PI is requested to submit study protocol or protocol-related document with a new version number and date.

3.4.1.10 The secretariat staff receives the continuing review application with a new version number and date. The newly approved documents will supersede previous versions of the study protocol or protocol-related document. The secretariat staff stores the signed continuing review application documents in the study protocol folder.

3.4.2 IB updates

3.4.2.1 The IB may be updated from time to time. The updated IB has to be approved by JKEUPM prior to its implementation.

3.4.2.2 The request for approval is facilitated through the submission of a letter to the PASC Chair with the updated IB. PASC makes decisions on all expeditable items but only recommends decisions on full board items.

3.4.2.3 PASC Chair to assess the urgency of the update. If PASC Chair assesses it to be needing immediate action, he/she forwards his/her recommendations to the JKEUPM Chair for immediate action and results will be communicated to the PI immediately.

3.4.2.4 A full board review is necessary if the proposed changes to IB increases risk to study participants, as assessed by the PASC, such as new data of the investigational product, which may include but is not limited to:

a. Changes in method of dosage formulation, (e.g. oral changed to intravenous).
b. Significant decrease or increase in dosage amounts.
c. Changes of dose frequency.

d. New non-clinical and/or clinical data.

3.4.2.5 If the proposed updated IB is with minimal risk, it can be approved by PASC.

3.4.2.6 However, if the proposed updated IB is with high risk (i.e. full board item), PASC Chair to present to JKEUPM members for deliberation.

3.4.2.7 The PI is notified of the JKEUPM decision on the updated IB. The PI may be required to modify the IB, or submit additional documents. The PI is requested to submit an amended IB with a new version number and date.

3.4.2.8 The secretariat staff receives the updated IB or IB-related documents with a new version number and date. The newly approved documents will supersede previous versions of the study IB or IB-related document(s). The secretariat staff stores the signed and approved documents in the study protocol folder.

3.4.3 Insurance updates

3.4.3.1 The insurance may be updated from time to time. The updated insurance has to be approved by JKEUPM prior to its implementation.

3.4.3.2 The request for approval is facilitated through the submission of a letter to the PASC Chair with the updated insurance. PASC makes decisions on all expeditable items but only recommends decisions on full board items.

3.4.3.3 PASC Chair to assess the urgency of the update. If PASC Chair assesses it to be needing immediate action, he/she forwards his/her recommendations to the JKEUPM Chair for immediate action and results will be communicated to the PI immediately.

3.4.3.4 A full board review is necessary if the proposed changes to insurance increases risk and/or diminishes the coverage to study participants, as assessed by the PASC, such as a changes and conditions to amount and nature of coverage, which may include but is not limited to:

a. Reduce number of subjects.
b. Additional treatment or the deletion of treatments.
c. Nature of treatments that are covered might change.
d. Duration of hospitalisation.
e. Change of daily limit.
f. Procedures (eg imaging) that are covered.
g. Change to follow up coverage.
h. Change of nature of injuries/illnesses covered.
i. Significant change in the number of subjects covered.

3.4.3.5 If the proposed updated insurance is with minimal risk, it can be approved by PASC.

3.4.3.6 However, if the proposed updated insurance is with high risk (i.e. full board item), PASC Chair to present to JKEUPM members for deliberation.

3.4.3.7 The PI is notified of the JKEUPM decision on the updated insurance. The PI may be required to modify the insurance coverage, or submit additional documents. The PI is requested to submit an updated insurance with a new version number and date.

3.4.3.8 The secretariat staff receives the updated insurance or insurance-related documents with a new version number and date. The newly approved documents will supersede previous versions of the study insurance or insurance-related document(s). The secretariat staff stores the signed and approved documents in the study protocol folder.

3.4.4 Study Protocol Amendment

3.4.4.1 A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Approval should be obtained from the JKEUPM that issued the ethical clearance or approval prior to the implementation of an amendment.

3.4.4.2 A study protocol amendment is facilitated through the submission of a letter to the PASC Chair with the amended study protocol or protocol-related documents. PASC makes decisions on all expeditable items but only recommends decisions on full board items.

3.4.4.3 PASC Chair to assess the urgency of the amendment approval. If PASC Chair assesses it to be needing immediate action, he/she forwards his/her recommendations to the JKEUPM Chair for immediate action and results will be communicated to the PI immediately.

3.4.4.4 A full board review is necessary if the proposed study protocol amendment increases risk to study participants, as assessed by the PASC, such as a change in study design, which may include but is not limited to:

a. Additional treatment or the deletion of treatments.
b. Any changes in inclusions/exclusion criteria.
c. Changes in method of dosage formulation, (e.g. oral changed to intravenous).
d. Significant change in the number of subjects.
e. Significant decrease or increase in dosage amounts.

3.4.4.5 If the proposed study protocol amendment is with minimal risk, it can be approved by PASC.

3.4.4.6 However, if the proposed study protocol amendment with high risk (i.e. full board item), PASC Chair to present to JKEUPM members for deliberation.

3.4.4.7 The PI is notified of the JKEUPM decision noting which amended documents are approved for use. The PI may be required to modify the protocol, provide additional information, or submit additional documents. The PI is requested to submit an amended study protocol or protocol-related document with a new version number and date.

3.4.4.8 The secretariat staff receives the amended study protocol or protocol-related document with a new version number and date. The newly approved documents will supersede previous versions of the study protocol or protocol-related document. The secretariat staff stores the signed and approved documents in the study protocol folder.

3.4.5 Final Report

3.4.5.1 Upon completion of the study, the PI should provide the JKEUPM with a summary of the outcome of the study in a form of an end of study report through **JKEUPM FORM 3.2: STUDY FINAL REPORT**.

3.4.5.2 All the final report will be sent to the PASC together with the originally approved protocol for approval. All submissions will be reviewed and finalized by PASC at the following meeting.

3.4.5.3 Chair of PASC to present the reports to JKEUPM members for deliberation.

3.4.5.4 The PI is notified of the JKEUPM decision **fourteen (14) working days** after the Full Board meeting. The PI may be required to provide additional information or submit additional documents, in which case the final report may be accepted, but action regarding archiving may be deferred pending submission of results of the study. If the final report is approved, the PI is informed of the following:

a. The study protocol is classified as inactive.
b. Ethical clearance is expired effective on the day of the Full Board meeting.
c. Study protocol records will be made available for **three (3) years** for non-clinical trial and **seven (7) years** for clinical trial in the archives after the expiry date.

3.4.6 Study Protocol Noncompliance (Deviation/Violation) Report

3.4.6.1 The PI should document, explain, and report to the JKEUPM any noncompliance from the approved protocol, whether minor or major, at the soonest possible time.

3.4.6.2 The PI may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior JKEUPM approval, but must submit as soon as

possible, a report of deviation or change, the reasons for it, and submit a study protocol amendment(s).

3.4.6.3 Reporting of study protocol noncompliance is facilitated through the submission of **JKEUPM FORM 3.3: STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT**, together with documents deemed relevant by the PI to clarify information indicated in the report.

3.4.6.4 Reporting of study protocol noncompliance is facilitated through the submission of **JKEUPM FORM 3.3: STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION) REPORT**, together with documents deemed relevant by the PI to clarify information indicated in the report.

3.4.6.5 All noncompliance reports will be sent to the PASC together with the originally approved protocol for approval**.** All submissions will be reviewed by PASC at the following meeting.

3.4.6.6 Chair of PASC to present study protocol noncompliance reports to JKEUPM members for deliberation. JKEUPM may suspend ethical clearance or subject recruitment until noncompliance issues are addressed. JKEUPM may opt to withdraw ethical approval under the following circumstances:

a. Fraud (e.g. data manipulation, major protocol violation, etc)
b. Unresolved serious safety issues

3.4.6.7 The PI is notified of the JKEUPM decision **fourteen (14) working days** after the Full Board meeting. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

3.4.6.8 The Secretariat Staff stores the signed study protocol noncompliance report documents in the study protocol file folder.

3.4.7 Early Study Termination Application

3.4.7.1 An application for early study termination is submitted when a study approved by JKEUPM is being recommended for termination before its scheduled completion. This is done when the safety of the study participant is in doubt or at risk and also upon the request of the PI or the sponsor owing to the existence of unresolved situations.

3.4.7.2 Early study termination is facilitated through the submission of **JKEUPM FORM 3.4: EARLY STUDY TERMINATION APPLICATION FORM**, together with documents deemed relevant by the investigator to support or clarify information indicated in the application. This comprises the early study termination application package.

3.4.7.3 The Secretariat Staff places the early study termination application in the PASC report presentation at the next full board meeting.

3.4.7.4 The PI is notified of the panel decision **fourteen (14) working days** after the Full Board meeting, The PI may be requested to provide additional information or submit additional documents. If the application is approved, the PI is requested to complete and submit **JKEUPM FORM 3.2: STUDY FINAL REPORT**.

3.4.7.5 The Secretariat Staff stores the early study termination application documents in the study protocol file folder.

3.4.7.6 JKEUPM may opt for early study termination in the event of non-compliances that affect subjects' safety. PI will be notified through letter from Chair of JKEUPM. PI is required to submit a progress report and follow-up of participants who are still active in the study.

3.5 SERIOUS ADVERSE EVENT REPORTS WORKFLOW

<table>
<tr><th colspan="2">Activity</th><th>Responsibility</th></tr>
<tr><td colspan="2">Ensure completeness and receive serious adverse event (SAE) report/s
↓</td><td>Secretariat Staff</td></tr>
<tr><td colspan="2">Log report/s on Log of Submissions and SAE Database
↓</td><td>Secretariat Staff</td></tr>
<tr><td colspan="2">Forward reports to PASC Chair to assess urgent/non urgent SAE/SU SA Rs

** PI has to report to site HOD
↓</td><td>Secretariat Staff</td></tr>
<tr><td>URGENT
↓</td><td>NON-URGENT
(Assign to original primary reviewer*)
↓</td><td>PASC Chair</td></tr>
<tr><td>If the report needs immediate action, PASC Chair to assess/ recommend
↓</td><td>Forward to Primary Reviewer within 48 hours after receipt of reports
↓</td><td>Secretariat Staff</td></tr>
<tr><td>Forward PASC recommendation/s to the JKEUPM Chair for immediate action</td><td>Submit review to the secretariat staff seven (7) working days after receipt of SAE report
↓
Conduct PASC Meeting</td><td>Onsite: PASC Primary Reviewer, Secretariat

Staff,
Offsite: PASC

Chair, PASC Members</td></tr>
</table>

↓	↓	Secretariat Staff
	Present review in the JKEUPM meeting ↓	Primary Reviewer/ PASC Chair
	Deliberation on board action on the report/s ↓	JKEUPM Chair, JKEUPM Secretary, JKEUPM Members, Primary Reviewer
Communicate results to principal investigator ↓		Secretariat Staff
If no further action: send notification of decision to PI **If recommend further action:** send notification with recommendations to PI;		Secretariat Staff
Manage study protocol files		Secretariat Staff

* in the absence of the Primary reviewer, PASC to meet and deliberate

3.5.1 Management of the SAE report upon submission

3.5.1.1 Serious adverse events are events temporally associated with the subject's participation in research that meets any of the following criteria:

a. Results in death.
b. Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
c. Requires inpatient hospitalization or prolongation of existing hospitalization.
d. Results in a persistent or significant disability/ incapacity
e. Results in a congenital anomaly/ birth defect.
f. Any other adverse event that based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in the definition.

3.5.1.2 The PI must report serious adverse advents to the JKEUPM panel. All serious adverse events (SAEs) detected or being notified should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.

3.5.1.3 The PI must report suspected, unexpected, serious adverse reactions (SUSAR), and other documents deemed relevant by the investigator to clarify information indicated in the report.

3.5.1.4 The Secretariat Staff collates all the serious adverse event(s) reports and encodes data in the **JKEUPM FORM 3.5: SAE/ SUSARs REPORT**.

3.5.2 Processing of Serious Adverse Events Reports

3.5.2.1 For all Serious Adverse Event(s) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports, the secretariat staff forwards the report comprised the following documents to the PASC Chair immediately:

a. **JKEUPM FORM 3.5: SERIOUS ADVERSE EVENTS REPORTS/CIOMS Form**.
b. Latest Investigator's Brochure.
c. Protocol Summary.
d. Other supporting documents, if any.

3.5.2.2 PASC Chair to assess whether the reports are urgent or non-urgent. If PASC Chair assesses the reports which require immediate action, he forwards his recommendation/s to the JKEUPM Chair for immediate action and results will be communicated to the PI immediately.

3.5.2.3 In non-urgent reports from both on and off sites, PASC will assign the original primary reviewer to assess the reports. The reports will be forwarded to the primary reviewer within 48 hours after receipt of reports.

3.5.2.4 For all non-urgent reports, the review should be submitted to the secretariat staff **seven (7) working days** after receipt of SAE report package and the review will be discussed in the PASC meeting. During the meeting, the PASC may recommend any of the following actions:

a. No further action
b. Recommend further action.

Further actions may include, but not limited to the following:

i. Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;
ii. Recommend implementation of additional procedures for

protecting/safeguarding participants;

iii. Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency);

iv. Recommend suspension of the entire study.

3.5.2.5 The review will be presented at the JKEUPM meeting and the JKEUPM Chair calls for a decision on the SAE report with respect to the recommendations of the PASC. The full board may require any of the following actions:

a. No further action
b. Requires further action

3.5.3 Communication of results

3.5.3.1 The PI is notified of the panel decision **14 working days** after the Full Board meeting, noting panel action on the Serious Adverse Event/s Report through an action letter.

3.5.3.2 The PI may be requested to provide additional information, submit additional documents, or implement corrective action. The PI is required to follow up on the final status of the subjects and report to JKEUPM.

3.5.4 Files management

3.5.4.1 The Secretariat Staff stores the signed serious adverse event/s report in the study protocol file folder.

3.5.4.2 Files are managed in accordance with SOP 4: Active Files.

3.6 SITE VISIT WORKFLOW

Activity	Responsible Person
Select study sites to visit ↓	JKEUPM
Notify PI of date of "site visit" ↓	JKEUPM Chair
Create Site Visit Team ↓	JKEUPM
Conduct Site Visit ↓	Site Visit Team
Present findings during full board meeting ↓	Visit Team Chair
Communicate results of Site Visit and subsequent panel action to PI ↓	Secretariat Staff
Manage Site Visit documents	Secretariat Staff

3.6.1 Selection of Study Sites

3.6.1.1 Study sites may be selected for Site Visits based on the following criteria:

a. The nature of the study being conducted (i.e. high risk studies).
b. Frequent non-submission or failure to submit continuing review requirements.
c. Reports of major protocol noncompliance.
d. Significant number of serious adverse events.
e. Reports of complaints from study participants.
f. Site visits may be conducted upon recommendation of the JKEUPM.

3.6.1.2 Study sites may also be selected for Site Visit upon recommendation of the PASC.

3.6.1.3 A decision for Site Visit is deliberated on during a full board meeting.

3.6.2 Notification of PI of date of site visit

3.6.2.1 The JKEUPM Chair, through the Secretariat, informs the PI at least **fourteen (14) working days** before the scheduled visit through a letter.

3.6.2.2 The letter provides Site Visit schedule details and instructions on what the PI needs to prepare such as documents and files that will be used for the Site Visit, as well as orderly preparation of the site.

3.6.3 Appointment of a Site Visit Team

3.6.3.1 A Site Visit Team is organized for each site visit.

3.6.3.2 The members of this team are assigned by the JKEUPM Chair.

3.6.3.3 The Site Visit Team should consist of at least three (3) people: one (1) JKEUPM member, one (1) PASC Member and one (1) other member preferably the primary reviewer of the protocol or of the SAE.

3.6.4 Conduct of Site Visit

3.6.4.1 Upon arrival at the study site, the Site Visit Team uses **JKEUPM FORM 3.6: SITE VISIT REPORT FORM** to do the following:

a. Review the study protocol.
b. Review the informed consent documents and verify if the site is using the most recently approved version.

c. Ask the PI or staff to explain the informed consent process.
d. Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved.
e. Verify security, privacy, and confidentiality of the documents at the study site.
f. Observe facilities in the study site.
g. Make an overall determination of the protection of the rights, safety, and welfare of human participants in the study.

3.6.4.2 At the end of the visit, the Site Visit Team will:

a. Discuss the findings with the research team
b. Solicit feedback

3.6.5 Presentation of findings at PASC Meeting

3.6.5.1 The Site Visit Team completes **JKEUPM FORM 3.6: SITE VISIT REPORT FORM** which should reflect the consensus opinion of the Site Visit Team members and submits it to the Secretariat not later than **seven (7) working days** after the Site Visit.

3.6.5.2 The Secretariat Staff places the Site Visit Report in the agenda of the next PASC meeting.

3.6.5.3 During the meeting, the Secretariat Staff distributes the completed **JKEUPM FORM 3.6: SITE VISIT REPORT FORM** to Panel Members along with the meeting agenda.

3.6.5.4 The Site Visit Team Chair presents the findings to the PASC.

3.6.5.5 PASC will review the outcomes of the site visit team findings and present to the Full Board meeting.

3.6.5.6 The JKEUPM Panel deliberates on the implications of results of the Site Visit on the rights, safety, and welfare of the study participants; and makes an overall determination of protocol compliance in the study site.

3.6.6 Communication of results

3.6.6.1 The PI is notified of the panel decision **fourteen (14) working days** after the Full Board meeting.

3.6.6.2 The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

3.6.7 Site Visit files management

3.6.7.1 The Secretariat Staff stores the Site Visit documents in the study protocol file folder.

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4. DOCUMENTATION

4.1 OBJECTIVES

This SOP describes how the JKEUPM manages documentation and communication of review, such as how the minutes of the meetings are to be prepared, used, distributed, and filed; how to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication, how administrative records and JKEUPM administrative documents (exclusive of study protocol files) are processed, stored, or disposed of; how active and inactive or archived study protocol files are maintained, including their amendments and/or modifications; and how to handle original documents and copies of documents in order to protect confidentiality of documents.

4.2 SCOPE

This SOP is applicable to regular review panels, to minutes of the meeting, all communication records related to study protocols with JKEUPM approval or undergoing JKEUPM review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least three (3) years after completion of non-clinical trial and 7 years for clinical trial so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, JKEUPM documents, and correspondences.

4.3 RESPONSIBILITIES

The Secretariat Staff, under the supervision of the Member Secretary, has the primary responsibility for study protocol and administrative documentation and archiving of the related documents. The Chair is responsible for final approval of documents.

4.4 MINUTES OF THE MEETING WORKFLOW

Activity	Responsibility
Prepare the template of the Minute s of the Meeting ↓	Secretariat Staff
Prepare draft of Minute s ↓	Secretariat Staff /Member Secretary
Approve the Minutes ↓	Member Secretary, Chair
Store the approved Minutes	Secretariat Staff

4.4.1 Preparation of the template of the Minutes of the Meeting

4.4.1.1 The Member Secretary and Secretariat Staff use the **FORMAT OF THE MINUTES OF THE MEETING (DOC 1)** to organize a template of the minutes ahead of the meeting date.

4.4.1.2 In case of a special review panel meeting, the **FORMAT OF THE MINUTES OF THE MEETING (DOC 1)** will be adjusted to actual content requirements of the meeting of this type of panel.

4.4.1.3 All the relevant identifying information should be filled up such as standard text in the regular sections and relevant study protocol information.

4.4.1.4 The draft of the minutes of the meeting is generated as the meeting progresses.

The Member Secretary in charge of documentation notes all board opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.

4.4.1.5 The minutes of the meeting is recorded using an audio tape recorder and will be transcribed following the format of the minutes.

4.4.2 Preparation of the draft of the Minutes

4.4.2.1 Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.

4.4.2.2 The Secretariat Staff in charge of documentation submits a complete draft of the minutes to the Member Secretary within fourteen (**14) working days** after the meeting for content corrections and finalization. The finalized draft is sent to the Chair immediately for approval.

4.4.2.3 The following information must be indicated in the minutes:

a. Date and venue of meeting
b. Members attendance (members present and absent)
c. Guests and observers attendance
d. Time when the meeting was called to order
e. Chair of the meeting
f. Items discussed per Meeting Agenda
g. Name and signature of the Secretary to indicate that contents have been verified and corrected
h. Name and signature of the Chair to indicate approval
i. Date of approval by the Chair

4.4.3 Approval of the Minutes

4.4.3.1 The Chair approves the draft of the minutes by affixing his/her signature and the date he/she signs the minutes.

4.4.3.2 Upon approval of the draft of the minutes, the Secretariat staff transfers contents of the *Conclusions and Recommendations* section (per study protocol discussed) into the forms accordingly.

4.4.4 Storage and Distribution of the Minutes

4.4.4.1 The Secretariat Staff files the original copy of the minutes in the Meeting Folder. The minutes will be distributed to all members within **7 working days** before the next full board meeting.

4.4.4.2 The minutes will be presented in the next full board meeting for panel approval.

4.5 STUDY PROTOCOL COMMUNICATION RECORDS WORKFLOW

Activity	Responsibility
Sort all communications received and issued by the JKEUPM ↓	Secretariat Staff
Record the details of the communication ↓	Secretariat Staff
Store communication files	Secretariat Staff

4.5.1 Sorting of all communications received and issued by the JKEUPM

4.5.1.1 Communications can come in the form of letters, official memoranda, or emails.

4.5.1.2 The Secretariat Staff sorts all communications received and prepares them for recording.

4.5.2 Recording of the details of the communication

4.5.2.1 The usage of correction pen on all documentation are not allowed. Correction on the documentation should be crossed out. Amendment to the correction should be signed and dated next to the correction.

4.5.3 Storage of communication records

4.5.3.1 The Secretariat Staff files a copy of the communication in the study file.

4.5.3.2 For SAE Files, the secretariat staff stores the signed serious adverse event/s report in the study protocol file folder.

4.5.3.3 The Secretariat Staff then writes in the protocol folder contents index as each communication is filed.

4.6 ADMINISTRATIVE RECORDS WORKFLOW

Activity	Responsibility
Compile administrative documents and/or records ↓	Secretariat Staff
Sort and store documents ↓	Secretariat Staff
Dispose unnecessary copies	Secretariat Staff

4.6.1 Compilation of administrative records

4.6.1.1 The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operations of the JKEUPM such as:

a. Reference materials and guidelines
b. Standard Opening Procedures
c. Communications issued to and received from persons other than principle investigators, on matters that are not related to any study protocols
d. JKEUPM members and staff files (CVs, Appointment letters, signed LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS (JKEUPM FORM 1.1), TRAINING RECORDS (JKEUPM FORM 1.2), Certificates of training
e. Forms (uploaded in the RMC website)
f. Minutes of General Assembly

4.6.1.2 These documents are maintained separately from study protocol-related documents.

4.6.2 Sorting and storage of documents

4.6.2.1 The Secretariat Staff labels and files administrative documents sequentially.

4.6.2.2 Guidelines are filed chronologically.

4.6.2.3 SOP Manuals are filed chronologically.

4.6.2.4 Important communications are filed in the communications folder and recorded chronologically.

4.6.2.5 Members' and staff files are filed according to the name list pasted in the file

4.6.2.6 Signed LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS (JKEUPM FORM 1.1) and training certificates are filed chronologically under member's and staff's file.

4.6.2.7 TRAINING RECORDS must be updated as each training certificate is submitted by the member or staff for filing.

4.6.3 Disposal of unnecessary copies

4.6.3.1 Removed document files are shredded and permanently deleted from electronic and physical files.

4.7 ACTIVE FILES WORKFLOW

Activity	Responsibility
Create a coding system for active files ↓	JKEUPM
Organize the contents of the active study files ↓	Secretariat Staff
Maintain the active study files	Secretariat Staff

4.7.1 Creation of coding system for active study files

4.7.1.1 Active files are study protocols that have been received by the JKEUPM Secretariat and are either undergoing review (full board or expedited) or approved by the respective JKEUPM Panel.

4.7.1.2 All study files are coded as UPM/TNCPI/RMC/1.4.18.2/ JKEUPM-YYYY-000, where UPM/TNCPI/RMC/1.4.18.2 follows the university ISO requirement and YYYY represents the year and 000 represents the number of file.

4.7.1.3 The study file code should appear prominently on the study protocol folder.

4.7.2 Organization of contents of active study files

4.7.2.1 Study files are encoded into the Study Protocol Database.

a. List of documents in the non-clinical study file:

- Form 2.1 (Checklist for Applicants)
- Form 2.3 (JKEUPM application form)
- Proposal
- Executive summary
- Questionnaire (if any) –version English/Malay or Others
- Form 2.4 (Respondent's Information Sheet and Consent) - version English/Malay or Others
- Form 2.5 (Respondent's Information Sheet and Guardian's/Parent's Consent) - version English/Malay or Others
- Supporting document (if any)
- CVs of researcher
- Approval Letter

b. While the following documents in the clinical trial study file:

Compulsory:

- Good Clinical Practice (GCP) certificate
- Investigator's brochure (IB)
- Signed clinical study protocol and amendments
- Sample case report form
- Informed consent form
- Insurance statement
- Subject compensation
- Curriculum vitae and relevant documents of qualification of PI and co-PIs
- Certificates of analysis of investigational products
- Decoding procedures for blinded trials
- Respondent information sheet
- All available safety information
- All questionnaires used

If Applicable:

- Trial Initiation monitoring report
- Advertisement for subject recruitment
- Signed agreement between parties involved
- Shipping records for investigational products
- Pre-trial monitoring report
- Material transfer agreement (MTA)

4.7.2.2 The Secretariat Staff puts study protocol files in file folders upon processing of the submission of the study protocol.

4.7.2.3 Folders are then kept in secure cabinets according to the year and faculty.

4.7.3 Maintenance of study protocol files

4.7.3.1 The Secretariat Staff files all the aforementioned documents in the study folder as they come.

4.7.3.2 The Secretariat Staff stamps the receiving date on all documents before putting them in the folders.

4.7.3.3 All File folders are maintained in the cabinet until the **STUDY FINAL REPORT (JKEUPM FORM 3.2)** is approved by the JKEUPM Panel.

4.7.3.4 The Secretariat Staff maintains Panel Files cabinets under the supervision of the Member Secretary.

4.7.3.5 The pest control activities in the file storage room will be carried out periodically once a year.

4.8 ARCHIVED (INACTIVE/COMPLETED/TERMINATED) FILES WORKFLOW

Activity	Responsibility
Manage completed/inactive /terminated study files ↓	Secretariat Staff
Sort administrative documents to be archived ↓	Secretariat Staff
Establish archived documents retrieval process	Secretariat Staff

4.8.1 Management of Archived (inactive/completed/terminated) study files

4.8.1.1 Archived (Inactive/Completed/Terminated) study files are either:

a. Study protocols with approved (by the JKEUPM) final reports, or
b Approved study protocols declared Inactive by the review panel if no communication is received from study team for a period of twelve months.
c. Study protocols for initial review with resubmissions beyond 90 days from date of action letter.

4.8.1.2 Upon receipt of **JKEUPM FORM 3.2: STUDY FINAL REPORT**, the JKEUPM panel reviews it in accordance with SOP III.

4.8.1.3 Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

4.8.1.4 All completed study files will be colour coded as red by placing the sticker on the file.

4.8.2 Retrieval of documents

4.8.2.1 Only authorized JKEUPM Secretariat Staff can retrieve documents either from active study files or from the archives.

4.8.2.2 Active or inactive study files can be borrowed, upon written request by the PI or the JKEUPM personnel, and only for room use.

4.9 Confidentiality of study files and JKEUPM documents Workflow

Activity	Responsibility
Classify documents as confidential ↓	JKEUPM
Request access to JKEUPM documents ↓	Members, non-members
Reproduce confidential documents ↓	Secretariat Staff
Maintain log of copies issued	Secretariat Staff

4.9.1 Classification of documents as confidential

4.9.1.1 Access to confidential documents is restricted by the JKEUPM to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.

4.9.1.2 The JKEUPM considers the following as confidential:

a. Study protocols
b. Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
c. Meeting Minutes
d. Decisions, action letters/notification of JKEUPM decision, approval letters
e. Study protocol-related communications

4.9.2 Access to confidential JKEUPM documents

4.9.2.1 All JKEUPM members and the staff with a signed **JKEUPM FORM 1.1**: **LETTER OF UNDERTAKING FOR JKEUPM COMMITTEE MEMBERS** can have access to JKEUPM confidential documents upon request.

4.9.2.2 Non-members can access specific documents upon formal request and completion/signing of **JKEUPM FORM 1.4: NON DISCLOSURE OF CONFIDENTIAL INFORMATION AND CONFLICT OF INTEREST.** The form requires the approval of the JKEUPM Chair. Regulatory authorities have full access to JKEUPM files provided it is within said authorities' mandate, and upon reasonable notice to make the files available.

4.9.2.3 All requests for access are recorded by the Secretariat Staff in the LOG OF REQUEST FOR COPIES OF DOCUMENTS (JKEUPM FORM 4.1) before the documents are released.

4.9.3 Reproduction of confidential documents

4.9.3.1 The Secretariat makes only the exact number of copies requested.

4.9.3.2 The recipient signs for the copies requested in the LOG OF REQUEST FOR COPIES OF DOCUMENTS (JKEUPM FORM 4.1) upon receipt of the copies.

4.9.4 Maintenance of log of copies

4.9.4.1 The Secretariat staff ensures the diligent recording of all document copies issued in the LOG OF REQUEST FOR COPIES OF DOCUMENTS [JKEUPM FORM 4.1].

4.9.4.2 This log is filed in a separate folder labelled Log of Copies Issued.

4.10 REVISING SOP WORKFLOW

Activity	Responsibility
Propose to revise the SOP ↓	JKEUPM Member/s
Review, discuss and approve the SOP draft revision in a full board meeting ↓	JKEUPM Member/s
Approve and sign the SOP revision ↓	Chair/DVC
File and distribute the revised SOP ↓	Secretariat Staff
Archive the superseded SOP	Secretariat Staff

4.10.1 JKEUPM Member/s proposes to revise the SOP

4.10.1.1 As the JKEUPM sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical is not considered as substantial; a change in the identifier of an SOP is considered substantial. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.

4.10.1.2 When an SOP is difficult to understand or does not cover what it should, a revision may become necessary. The SOP may be reviewed regularly by the Member Secretary every two years.

4.10.1.3 Secretariat or any member of the board may propose for the revision of the SOPs and submit a written proposal to the Member Secretary.

4.10.1.4 Any proposal for revision must be written and submitted by the Member Secretary/Secretariat to the board for review, approval, coding, and inclusion into the document.

4.10.2 JKEUPM Members review, discuss and approve the SOP draft revision in a full board

meeting

4.10.2.1 When the need for a revision of SOP has been identified and agreed on, a draft will be written by a Secretariat. A draft of the revised SOPs will be discussed by the JKEUPM members. The draft version will be reviewed by the Chair who will submit it to the Deputy Vice Chancellor for Research and Innovation for approval.

4.10.2.2 The Secretariat drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.

4.10.2.3 The Chair submits the drafts to the full board review where the JKEUPM members deliberate on the draft.

4.10.3 The IEC Chair and the VCR shall approve and sign the SOP revision

4.10.3.1 The Chair submits the approved draft to the Deputy Vice Chancellor for Research and Innovation for final approval.

4.10.3.2 The Deputy Vice Chancellor for Research and Innovation approves the revised SOP by signing on the appropriate section of the cover page.

4.10.3.3 The approved revised SOP will be implemented from the date of approval by the Deputy Vice Chancellor for Research and Innovation.

4.10.4 The JKEUPM Secretariat files and distributes the revised SOP

4.10.4.1 Upon approval of Deputy Vice Chancellor for Research and Innovation, the Secretariat distributes the revised SOP to JKEUPM members, updates the electronic SOP manual, and publishes the SOP through the Deputy Vice Chancellor for Research and Innovation website.

4.10.4.2 The Secretariat maintains the originally signed updated SOP manual in the Deputy Vice Chancellor for Research and Innovation office and retains one copy of the originally signed outdated versions.

4.10.4.3 The JKEUPM Secretariat collects the old SOP manuals in exchange of the revised manual.

4.10.4.4 The JKEUPM Secretariat includes the revised SOP in the SOPs manual that is currently used.

4.10.5 The JKEUPM Secretariat archives the superseded SOP

4.10.5.1 The Secretariat archives the superseded version of the SOP in the historical file.

4.10.5.2 Superseded SOPs are clearly marked “superseded" with the year of archiving stamped in the cover page.

4.10.5.3 Outdated SOPs are considered a permanent file.

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA

5. GLOSSARY

Terms	Definition
A	
Adverse Event	Any unfavorable change that may affect a subject during or after a clinical trial, the change is not necessarily caused by the investigational product. Includes physical signs and symptoms, abnormal laboratory findings, change in vital signs, a new condition or illness, or the worsening of a condition or illness that was present before product use. Also called adverse experience. When a causal relationship has been established between a product and the AE, the AE is referred to as an adverse drug reaction (causal relationship with a drug) or an adverse device effect (causal relationship with a medical device)
Amendment	See protocol Amendment
Applicant	The person who completes the ethics application form.
Approval	The affirmative decision of the Institutional Review Boards that the clinical trial has been reviewed and may be conducted at the institution site within the constrains set forth by the Institutional Review Boards, the institution, Good Clinical Practices (GCP), and the applicable regulatory requirement.
C	
Case Report Form (CRF)	A printed, optical, or electronic document used to record protocol-required information for each subject in the study
Clinical Practice	A form of research designed to find out the effects of an intervention, including treatment of diagnostic device.
Clinical Trial	A written description of a trial/study of any therapeutic, prophylactic, diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report
Compensation	Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research
Compliance	Adherence to protocol requirements, standards of good clinical practice, and applicable regulations

Confidentiality	Prevention of unauthorized disclosure of a sponsor's proprietary information or of a subject's identity and personal medication information
Conflict of Interest	Where personal interest may have the potential to influence the conduct of the research. This may include a personal, professional or financial interest in the outcomes of the research.
Consent	In this context, where a person has agreed to participate in research. Consent must be freely given (without coercion or pressure) and fully informed. Consent may be written, oral, implied or in certain circumstances may be given by a third party on behalf of the participant. See 'Informed Consent'.
Consent Form	Consent form is a document signed by the potential participant acknowledging their understanding of the information provided in the Letter to Participants and their agreement to participate in the research. In some cases, consent forms are read out loud and consent is given verbally.
Curriculum Vitae (CV)	A summary of an investigator's education, training, and experience, similar to a resume
D	
Data	Pieces of information. In relation to research this can include measurements, personal details and information, recorded conversations and interviews, surveys, observations and databases
Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or result of a trial, the factors affecting a trial, and the actions taken.
E	
Exclusion Criteria	Rules of eligibility that exclude an individual from participation in a study
Expedited Review	An expedited review is defined as an application that is not required to undergo the interview process. These applications will be circulated among members for comments and decision making.
F	

Full board review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting
G	
Good Clinical Practice	The standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. The standards provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentially of trial subjects are protected.
Guardian	An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care
Guidelines	Written principles and practices pertaining to applying the regulations. Although guidelines are an accepted standard of practice, they are not enforceable by law. FDA guidelines are
	applicable in the United States while International Conference on Harmonization (ICH) guidelines reflect an international movement to standardize practices across national borders.
H	
Harm	Harm may be physical, psychological, reputational or social
I	
Independent Consultant	A person who is not a member of JKEUPM and has special skill or knowledge/expertise in a particular field
Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a clinical trial/ non-clinical trial after having been informed of all aspects relevant to the subject's decision to participate. The Declaration of Helinski states that in any human research, each potential subject must be adequately informed of the aims, methods, anticipated benefits, potential hazards, and discomforts that study participation might entail. Informed consent is typically documented via a written, signed and dated consent form.
Institution	Any public or private entity or agency or medical or dental facility where clinical trials are conducted

Investigators	An individual who conducts a clinical study and directs the use, administration, and distribution of the investigational agent to a subject. When a team of individuals at a specific location conducts an investigation, the investigators is the responsible leader of the group. The investigator holds regulatory responsibility for the conduct of the trial at the investigative site. A c0-investigator is an individual who shares equal responsibility in conducting the trial at a site.
Investigational Product	A pharmaceutical form of an active ingredient including plant /animal-derived medicinal products or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication (off-label use), or when used to gain further information about an approved use.
L	
Low risk	The National Statement defines low risk research as where the only foreseeable risk is one of discomfort.
M	
Monitoring	The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections
Monitoring report	A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.
P	
Protocol	A document that identifies the plan or set of rules for conducting a specific clinical trial, and states the objectives, design, methodology, statistical considerations, and organization of a trial
Protocol Amendment	A written description of changes to, or the formal clarification of, a protocol.

Protocol Violation	A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Example of protocol violations may include the following: - Inadequate or delinquent informed consent - Inclusion/exclusion criteria not met - Unreported serious adverse events - Improper breaking of the blind - Use of prohibited medication - Incorrect or missing test - Mishandled samples - Multiple visits missed or outside permissible windows -
R	
Regulatory Authorities	Bodies having the power to regulate. In the Malaysian Guideline for Good Clinical Practice the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.
Research project	This is the term used to describe the overall research project. It incorporates the original application for funding and is distinct from the ethics protocol because it may involve more than the research outlined in the ethics protocol. A research project may have more than one ethics protocol associated with it, including animal ethics and biosafety protocols.
Review Panels	A committee, or other group that reviews and approves clinical studies at an investigative site. The primary responsibility of the committee is to ensure the protection of the rights and welfare of study participants. Also called Independent Review Committee, Ethics Committee, Human Protection Committee.
Risk	Risk refers to the magnitude and likelihood of harm arising as a result of research. It includes risk to the research participant(s), the researcher(s) and others who may be harmed as a result of the research. Risk may occur in a number of forms, including physical, emotional and reputational.
S	
Sponsor	An individual, company, institution, or organization that initiates a clinical investigation. The sponsor must comply with the responsibilities outlined in the regulations.

Standard Operating Procedure (SOP)	Detailed written instructions that provide a structure to ensure that activities are performed in a consistent manner.
Subject	An individual who participates in clinical research, either as a recipient of the test article or of the control. A subject may be either a healthy human or a patient.
Suspected Unexpected Serious Adverse Reactions Reports (SUSARs)	An adverse reaction, the nature of severity of which is not consistent with the applicable product information in the investigator's brochure for an unapproved investigational product, or on the package insert/summary of product characteristic for an approved product
Stigmatizing information	
V	
Vulnerable group/population	Individuals whose willingness to volunteer in a study may be unduly influenced by expectation of benefits, fear of retaliatory response, or lack of ability to understand trialrelated issues. Some groups identified as vulnerable subjects are prisoners, children, unborn fetuses, homeless persons, and those incapable of giving consent.