

Standard Operating Procedures

II. PROTOCOL REVIEW

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Authored by:	Assoc. Prof. Dr. Azlan Husin, Dr. Noor Aman A. Hamid, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin
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JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA)

UNIVERSITI SAINS MALAYSIA

T: 09-7673000, ext 2354/2362 F: 09-7672351

Email: jepem@usm.my <https://jepem.kk.usm.my/>

Document History

Author	Version	Date	Describe the main change
Assoc. Prof. Dr. Nor Azwany Yaacob, Assoc. Prof. Siti Hawa Ali, Prof. Wan Abdul Manan Wan Muda, Dr. Teguh Haryo Sasongko, Assoc. Prof. Dr. Mohtar Ibrahim, Assoc. Prof. Noraida Ramli, Pn. Zawiah Abu Bakar.	01	06-04-2014	First Draft
Prof. Dr. Narazah Mohd Yusoff, Assoc. Prof. Dr. Nor Azwany Yaacob, Assoc. Prof. Siti Hawa Ali, Dr. Teguh Haryo Sasongko, Pn. Zawiah Abu Bakar, Miss Nuraissafiah Ahmad	02	07-09-2015	Second Version – minor changes in the Form 2 (A), 2(B), 2(C) and 2 (D).
Prof. Dr. Hans Amin Van Rostenberghe and Mr. Mohd Bazlan Hafidz Mukrim	03	10-08-2016	Third Version – add clause in 6.3.2 section and administrative changes in the Form 2(A), 2(B), 2(C) and 2(D), 2(E), 2(F), 2(G), 2(H), 2(I) and 2(K) based on the recommendation made during inspection by BPFK on 12-14 April 2016.
Prof. Dr. Hans Amin Van Rostenberghe, Prof. Dr. Nik Hazlina Nik Hussain, Assoc. Prof. Siti Hawa Ali and Mr. Mohd Bazlan Hafidz Mukrim	04	10-05-2017	Fourth Version – add new template forms and minor changes in the SOP and application form. Also update the USM logo in all forms.
Prof. Dr. Hans Amin Van Rostenberghe, Prof. Dr. Nik	05	07-01-2019	Fifth Version – minor technical changes in point

Hazlina Nik Hussain and Mr. Mohd Bazlan Hafidz Mukrim			no. 4, 5, 6, 7 and 8. Also adding the page numbers to all the available forms.
Prof. Dr. Hans Amin Van Rostenberghe, Prof. Dr. Nik Hazlina Nik Hussain and Mr. Mohd Bazlan Hafidz Mukrim	06	10-07-2019	Sixth Version – minor technical changes in point no. 4, 5, 6, 7 and 8.
Prof. Dr. Narazah Mohd Yusoff, Assoc. Prof. Dr. Nazri Mustaffa, Dr. Noor Aman A. Hamid, Mr. Mohd Bazlan Hafidz Mukrim, Miss Abdah Khairiah Che Md Noor and Miss Nor Amira Khurshid Ahmed	07	30-08-2022	Seventh version – update includes online submission throughout this document
Assoc. Prof. Dr. Azlan Husin, Dr. Noor Aman A. Hamid, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	08	30-04-2026	Eighth version – minor changes in overall of the SOP II.

1. Objectives

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

2. Scope

The JEPeM-USM reviews research proposed by members of the school/unit, students, hospital staff, residents, fellows and other trainees and employees of Universiti Sains Malaysia (USM), and non-USM principal investigators (PIs).

This SOP applies to JEPeM-USM actions from the time of initial submission to the filing of the original study protocol package in the Active Study File cabinet. For softcopies and online submission, efilling system is used. This includes preparation of copies of the package for distribution to the reviewers and deliberations during committee meeting up to decision for ethical approval.

Note: Starting from 1st January 2021, JEPeM-USM has converted to online submission in phases, therefore this SOP has been modified to cater for online submission. The current default SOP for submission to JEPeM-USM is ONLINE but in special circumstances, hard copies/softcopy (email) submission can be accepted. The earlier online phase was softcopy submission via emails (started during COVID-19 pandemic) and later migrated to online submission system. As the JEPeM-USM online system consists of different components, namely Online submission package, Secretariat package, Panel Chair package, and Reviewer package. At the time of this update, only the Online Submission package and Secretariat package is operational. Therefore, update to this SOP is limited to these two packages. Other packages will be updated appropriately when ready.

3. Responsibilities

It is the responsibility of the Secretariat Staff to check the completeness, to manage the study protocol package and process the submission of the application.

It is the responsibility of the Panel Chairs to decide whether the study protocol is for full-board review, expedited review or exempted from review. The Chairperson/Deputy Chairperson/Panel Chair/Member Secretary is responsible for assigning primary reviewers. It is the responsibility of the Secretary to ensure that the deliberations and discussions are adequately documented.

Assigned reviewers are responsible for systematically review the study protocol, write their comments after each item listed in the study protocol and informed consent assessment forms, include consideration of relevant guidelines when doing the review, and submit review comments to the JEPeM-USM Secretariat Staff for further action.

The Principal Investigator (PI) is responsible for submitting a complete set of documents to the JEPeM-USM.

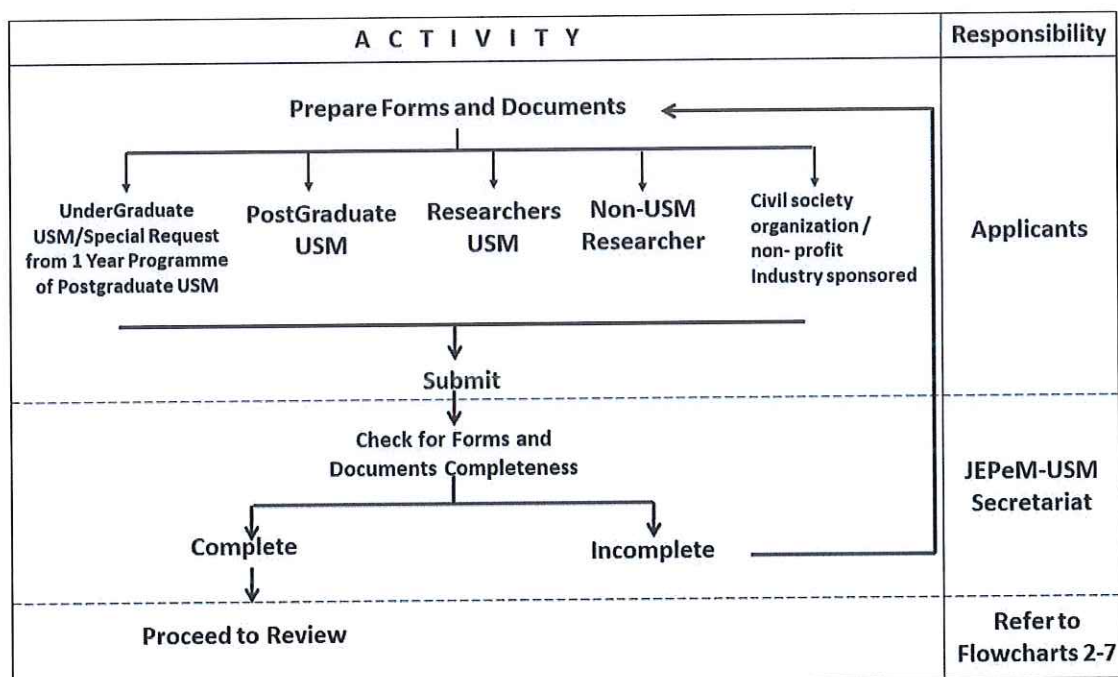
4. Submission process according to Principal Investigators (PI) categories (Flowchart 1)

The submission process is layout for different categories, the categories are:

1. Undergraduate/1 year Master programme
2. Postgraduates
3. USM staffs
4. Non-USM researchers
5. Civil Society Organisation/ Non-Profit/ Industry sponsored

Flow Chart 1

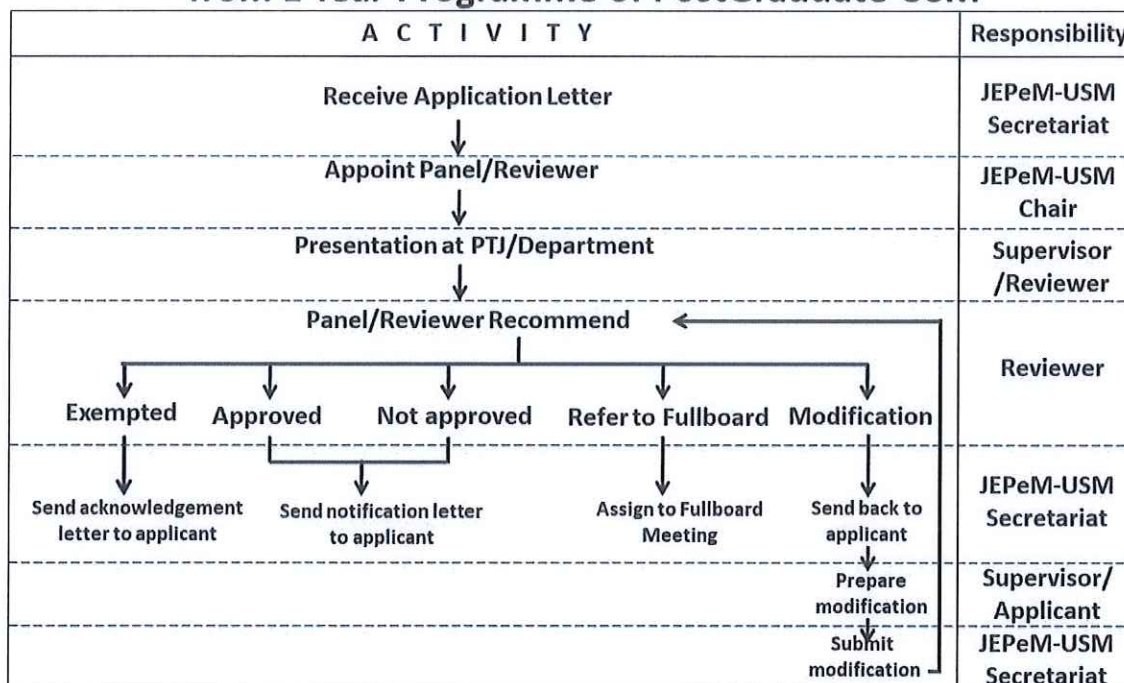
Flowchart 1 SOP II - Classification of PI



- 4.1. Based on Flowchart 1, the PI should classify their research protocol into one of the following:
- 4.1.1. Undergraduate/Special Request from 1 Year Programme of Postgraduate USM (Flowchart 2)
 - 4.1.2. Postgraduate USM (Flowcharts 3a and 3b)
 - 4.1.3. Researchers USM (Flowchart 4)
 - 4.1.4. Non-USM Researchers/civil society organization/Industry sponsored (Flowchart 5)

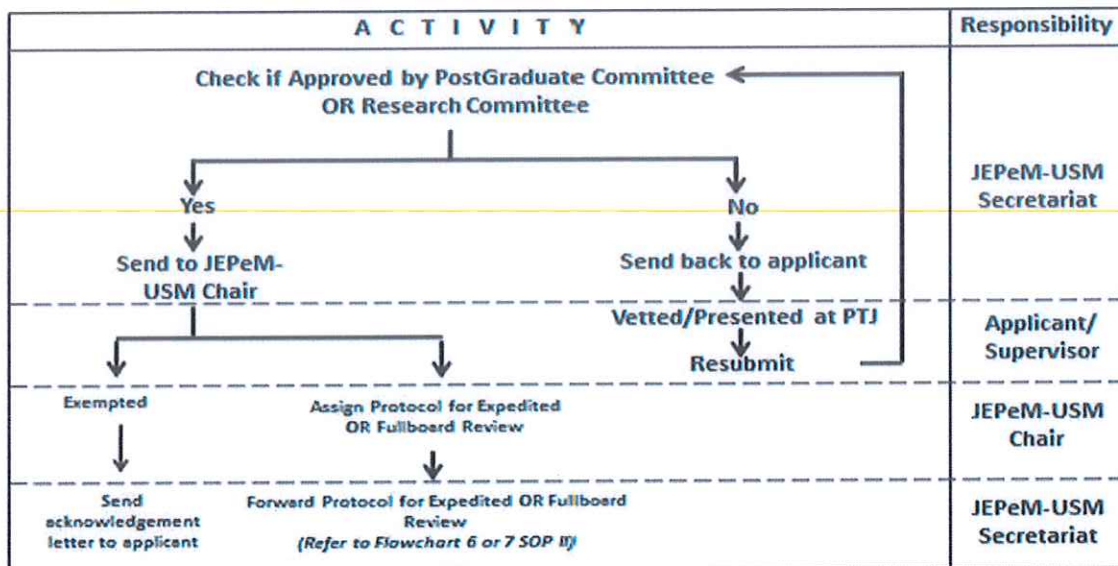
Flow Chart 2

Flowchart SOP II – Review UnderGraduate/Special Request from 1 Year Programme of PostGraduate USM

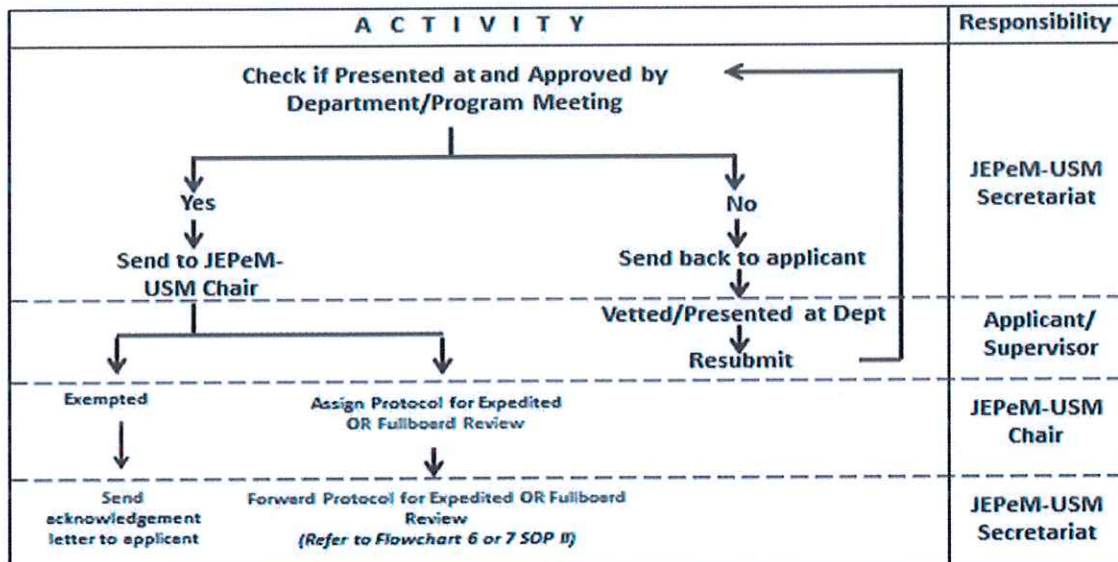


Flow Chart 3

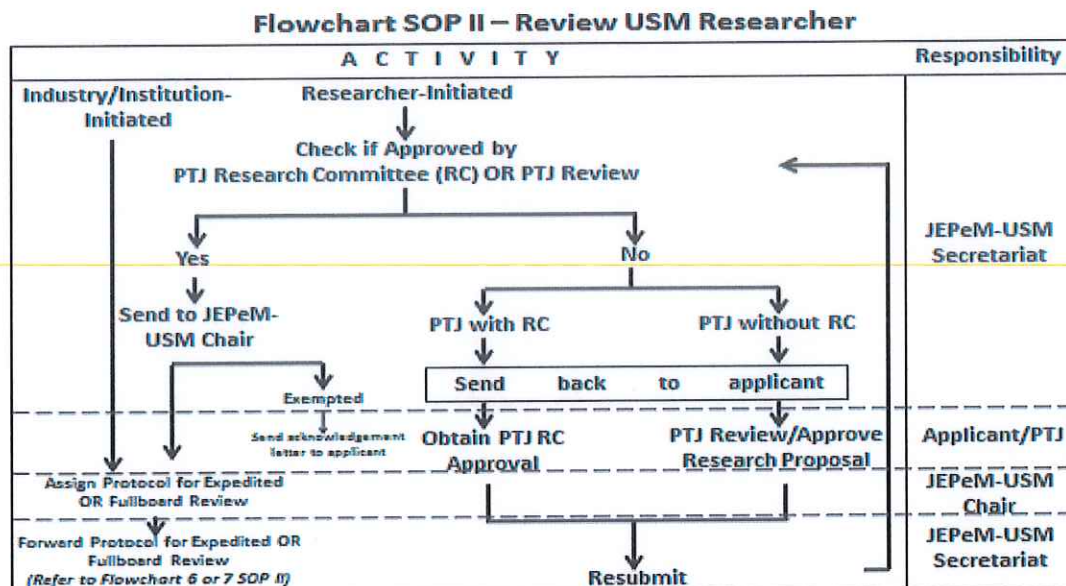
Flowchart 3 (a) – Review PostGraduate (By Research) USM



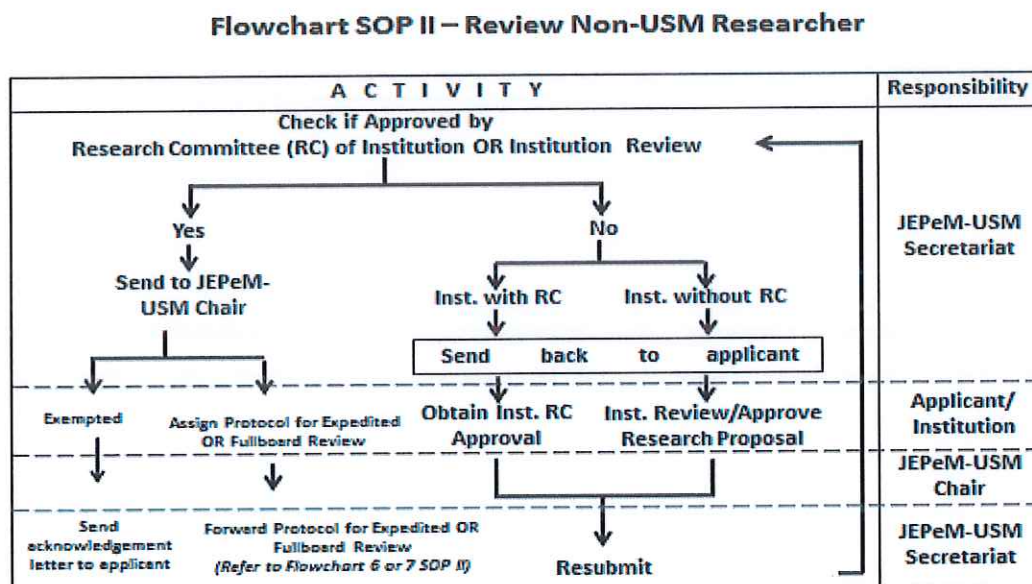
Flowchart 3b SOP II – Review PostGraduate (Coursework/Mixed Mode) USM



Flow Chart 4



Flow Chart 5



- 4.2. The classification should be indicated as such on Section I number 6 of **JEPeM-USM FORM 2(B)(i): Registration and Application Form**. For online package, the Principal Investigator should tick the appropriate field during new submission.

5. Submission of Application

An application for review or for ethical approval to JEPeM-USM should be submitted by a Principal Investigator responsible for the ethical and scientific conduct of the research.

5.1 Application Requirements

- Application should be submitted in the prescribed application form (**JEPeM-USM FORM 2(B)(i): Registration and Application Form**) to the JEPeM-USM secretariat office according to the classification of PI (please refer to section 4). For online application this can be done using 'online application package' (Refer Appendix A).
- The complete application should be submitted in English or Bahasa Malaysia.
- All relevant documents should be enclosed with application form (please refer to section 5.2).
- Applicants should submit **three (3) copies** (including one original copy) of the application forms and all the relevant documents. For online submission, only online package needs to be filled.
- Complete application shall be considered for review in the coming JEPeM-USM meeting not more than **thirty (30) working days** upon receipt by the Secretariat.
- The Secretariat will acknowledge the receipt of a complete application via email (if requested). Incomplete application will be returned to the applicant. For online submission an automated email via online package will be generated and sent to the PI.
- Secretariat will verify the completeness of application based on **JEPeM-USM FORM 2(A): Review Checklist**.
- Online: online submission package ensures completeness of forms in order to proceed with submission.
- For PI of USM students or staffs (as indicated in section 4.1.1, 4.1.2 and 4.1.3 above), before submission of their application to the committee, all research proposals must be reviewed and approved by the research committee or postgraduate committee of the respective department/school/centre/institution (refer to section IIA, IIB and III of **JEPeM-USM FORM 2(B)(i): Registration and Application Form**).
- For PI of researchers outside USM (as indicated in section 4.1.4 above), before submission, the research proposals must be approved by the Director/Dean/Head of

Institutions (refer to section IV of **JEPeM-USM FORM 2(B)(i): Registration and Application Form**).

- For online submission the PI is required to upload a signed endorsement form.
- For applicants of Undergraduate USM/Special Request from 1 Year Master Programme of Postgraduate USM, the list of project and a letter of request from Program Coordinator and should be submitted by the program coordinator to JEPeM-USM Chair.
- All medical research involving humans are encouraged to register with NMMR. However, for research involving drugs (interventional or observational), NMMR registration is mandatory.

5.2 Documents to be Submitted

5.2.1 The online submission package includes all the forms listed below according to categories. Content of the forms have been extracted into the online package.

5.2.2 For non-interventional research, the following documents are required to be submitted, in minimum, before the committee can evaluate the applications:

- JEPeM-USM FORM 2(A): Review Checklist
- JEPeM-USM FORM 2(B)(i): Registration and Application Form
- JEPeM-USM FORM 2(C)(ii): Study Protocol Assessment Form (for non-interventional study)
- JEPeM-USM FORM 2(D)(ii): Informed Consent Assessment Form (for non-interventional study)
- Full study protocol
- Study subject information sheet
- Study subject consent form
- Brief CVs of researchers (For Postgraduate Students, only CVs of PI and Main Supervisor are required).

5.2.3 For interventional and combination of interventional and non-interventional research, the following documents are required to be submitted, in minimum, before the committee can evaluate the applications:

- JEPeM-USM FORM 2(A): Review Checklist
- JEPeM-USM FORM 2(B)(i): Registration and Application Form
- JEPeM-USM FORM 2(C)(i): Study Protocol Assessment Form (for interventional study)
- JEPeM-USM FORM 2(D)(i): Informed Consent Assessment Form (for interventional study)

- Full study protocol
- Study subject information sheet
- Study subject consent form
- Brief CVs of researchers

5.2.4 For research involving commercial contract research/ interventional study/clinical trial, the following additional documents are required to be submitted with the application, wherever applicable, to be presented to the committee:

- Investigator's Brochure / Study Protocol
- Letter of indemnity/ insurance coverage
- A summary/synopsis of the protocol
- Case report forms, diary cards and other questionnaires intended for research participants.
- All significant previous decisions by other ECs or regulatory authority for the proposed study and an indication of modification (s) to the protocol made on that account. The reason for previous negative decisions should be provided.
- Financial contract
- Statement of publication rights
- Clinical Trial Agreement (CTA) between sponsor, researcher(s) and institution.
- Curriculum Vitae and Good Clinical Practice (GCP) Certificate

5.2.5 For applicants of Undergraduate USM/Special Request from 1 Year Programme of Postgraduate USM the following documents are required to be submitted, in minimum, before the committee can evaluate the applications:

- For Interventional Study
 - JEPeM-USM FORM 2(B)(ii): Request for Expedited Review Undergraduate
 - JEPeM-USM FORM 2(C)(i): Study Protocol Assessment Form for Interventional Study
 - JEPeM-USM FORM 2(D)(i): Informed Consent Assessment Form for Interventional Study
 - JEPeM-USM FORM 2(N)(i): Template protocol for Medical & Health Sciences or JEPeM-USM FORM 2(N)(ii): Template Protocol for Social & Others
 - JEPeM-USM FORM 2(O): Template for PIS and CF
 - JEPeM-USM FORM 2(L): Template CV for PI /Researchers
 - Good Clinical Practice (GCP) Certificate (for Interventional Clinical Trial

only)

- For Non – Interventional Study

- JEPeM-USM FORM 2(B)(ii): Request for Expedited Review Undergraduate
- JEPeM-USM FORM 2(N)(i): Template protocol for Medical & Health Sciences or JEPeM-USM FORM 2(N)(ii): Template Protocol for Social & Others
- JEPeM-USM FORM 2(O): Template for PIS and CF
- JEPeM-USM FORM 2(L): Template CV for PI /Researchers

- 5.2.6 Any related documents such as questionnaire, advertisements for recruitment and related pictures should also be submitted.
- 5.2.7 Study subject information sheet and informed consent form in English and other language(s) of the study subject should be enclosed. The study subject information sheet should provide adequate and complete information in understandable language to the participants (for the template, please refer to JEPeM-USM FORM 2(O): Template for Subject Information Sheet and Consent Form).
- 5.2.8 For applications from Undergraduate USM, the above are not applicable (refer to SOP II Section 5.1)

6. Initial Review Workflow

ACTIVITY	RESPONSIBILITY
Receive and manage study protocol submissions 	Secretariat Staff
Classify submission as exempted, expedited or full board review 	JEPeM-USM Chair/Panel chair
Assign primary reviewers	JEPeM-USM Chair

Send study protocol package to primary reviewers with I. JEPeM-USM FORM 2(A): Review Checklist II. JEPeM-USM FORM 2(B)(i): Registration and Application Form III. Full study protocol IV. Study Subject information sheet V. Study Subject consent form VI. Brief CVs of researchers (for those researchers outside USM) 	Secretariat Staff
Review the protocol and return accomplished JEPeM-USM FORM 2(C): STUDY PROTOCOL ASSESSMENT FORM and JEPeM-USM FORM 2(D): INFORMED CONSENT ASSESSMENT FORM to the Secretariat Staff	Primary Reviewers

- 6.1. The JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair/Member Secretary will assign at least 2 primary reviewers to review the submitted protocol. For interventional studies (Industry Sponsored), a community representative member will be appointed as one of the primary reviewer (where possible). Reviewers are selected on the basis of their expertise. The scientific/medical reviewer is tasked to review technical soundness and related ethical issues. In the case of clinical trials, a non- scientific reviewer can be represented by a member who is not a medical doctor. All interventional study is invited to Full Board and the community representative will be asked for an opinion on the PIS.
- 6.2. Primary reviewers can be assigned from the JEPeM-USM committee members and/or other expert(s) that is (are) appointed as the need arises (refer to SOP I).
- 6.3. Terms of Reference of primary reviewer
 - 6.3.1 After assignment of the primary reviewers, the complete application will be sent and reviewed by the primary reviewers within **ten (10) working days**. Exceptions may be given at the discretion of JEPeM-USM Chair.
 - 6.3.2 Upon receipt of the documents, primary reviewers can accomplish the acknowledgement receipt electronically. If no response is received within 3 working days, the task is considered to be accepted by the reviewers.
 - 6.3.3 Primary reviewers accomplish **JEPeM-USM FORM 2(C): STUDY PROTOCOL ASSESSMENT FORM** and **JEPeM-USM FORM 2(D): INFORMED CONSENT ASSESSMENT FORM** completely and comprehensively, and check for completeness of the

documentation and information about the PI/s, study sites, and other documents as required by the study protocol under review.

6.3.4 In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with the relevant national and international guidelines applicable in Malaysia (refer to <http://www.nccr.gov.my/index.cfm?menuid=26&parentid=17>) on:

- Use of biological materials
- Appropriate contracts or memoranda of understanding especially in collaborative studies
- Community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following if applicable: community consultation, involvement of local researchers and institutions in the study protocol design, analysis and publication of the results, contribution to development of local capacity for research and treatment, benefit to local communities, availability of study results, and benefit sharing.

6.3.5 The primary reviewers make a recommendation by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. The primary reviewers will recommend to the full board upon reviewed the protocol as follows:

- APPROVE – to be approved by the JEPeM-USM without the need of any modification of the documents submitted.
- MINOR MODIFICATIONS; PI Not To Be Invited for Presentation - the application need minor modification which does not need clarification from the PI. The application will be tabled in the next possible meeting (expedited review meeting or full board review meeting) and committee members will review the comments from both reviewers and make the decision based on the report from the reviewers.
- MINOR MODIFICATIONS; PI To Be Invited for Presentation – the application need minor modification but need clarification from the PI.
 - Minor modification for protocol assessment is defined as modification that would not change the study objective and methodology.
 - Minor modification for informed consent assessment is defined as modification that improves comprehension by the potential study subjects.
- MAJOR MODIFICATIONS – the application need major modification and need to be resubmitted. PI To Be Invited for Presentation during Full board meeting.
 - Major modification for protocol assessment is defined as modification that would change the study objective and/or methodology.
 - Major modification for informed consent assessment is defined as

modification that is related to vulnerability of the study subjects and completeness of information presented in the informed consent.

- NOT APPROVE -The study protocol is not ethically sound
- Reviewers submit their reports via email.

6.3.6 The consequences of these recommendations are discussed in SOP II Section 7.2 and 7.3.

6.3.7 In cases of re-review whereby the initial primary reviewer was not available for the period of review, the chair of the JEPeM-USM will assign a new reviewer. When a reviewer refused or reviewer who didn't review with only one reviewer comments available, the panel chair can make a decision on adequacy of the review for the Full Board.

6.3.8 JEPeM-USM must not reveal the name of reviewer to the PI and the research team members.

6.3.9 Primary reviewer shall not discuss the protocol with the PI and the research team members.

6.3.10 The report of primary reviewers will be presented, discussed and endorsed in the subsequent expedited meeting or full board meeting.

6.4 Elements of the Review

- 6.4.1 Protocol Assessment (based on the protocol assessment forms)
- Scientific merit of the study justified by the introduction & literature review
 - Study objectives
 - Research design
 - Sample size estimation
 - Sampling method
 - Inclusion and exclusion criteria
 - Vulnerability of the subject
 - Recruitment of subject and informed consent seeking
 - Assent form requirement
 - Randomization, matching, blinding
 - Study area
 - Research tool

- Data collection method
- Method of intervention
- Potential risks
- Direct & indirect benefit
- Duration of human subject involvement
- Proposed data analysis
- Declaration of conflict of interest
- Handling privacy & confidentiality issue
- Incentives/Honorarium/Compensation
- Collaborative study term of reference

6.4.2 Subject information sheet and Informed Consent Assessment

- List of all investigators involved
- Research title
- Purpose of the study
- Study procedures
- Responsibilities of the participant
- Expected duration of participation in the study
- Approximate number of participants in the study
- Foreseeable risks to participant/embryo/fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner
- Reasonably expected benefits; or absence of direct benefit to participants, as applicable
- Anticipated expenses, if any, to the participant in the course of the study
- Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled
- Statement that the study monitor(s), auditor(s), the USM-HREC Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of verification of clinical trial procedures and data
- Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality
- Plans to destroy collected biological specimen at the end of the study; if not,

- details about storage (duration, type of storage facility, location, access
- information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed
- Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development
- Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation
- Statement describing access of participant to the result of the study
- Statement describing extent of participant's right to access his/her records
- Foreseeable circumstances and reasons under which participation in the study may be terminated
- Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider
- Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study- related injury
- Statement that the JEPeM-USM (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:

Mr. Mohd. Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2352
Email : bazlan@usm.my/jepem@usm.my

- Online package includes all the above element

7. Protocol Review

7.1. Determination of the Type of Review

The JEPeM-USM Chair classifies the study protocol review pathway as either Exempted, Expedited Review or Full Board Review filtered through the following criteria:

7.1.1. Expedited Review criteria:

- 7.1.1.1 The research poses no more than minimal risk.
- 7.1.1.2 The study does not involve vulnerable populations.
- 7.1.1.3 The study does not involve the collection of stigmatizing information

- 7.1.1.4 The study uses anonymized or archived samples
- 7.1.1.5 The study which is involve with blood taking less than 20 cc/ml.
- 7.1.1.6 Continuing review of clinical trials that do not involve further recruitment of participants
- 7.1.1.7 Continuing review of studies previously classified under expedited review
- 7.1.1.8 Study protocol amendments that are administrative in nature and do not affect the study protocol

7.1.2 Full board review may include but not limited to the following:

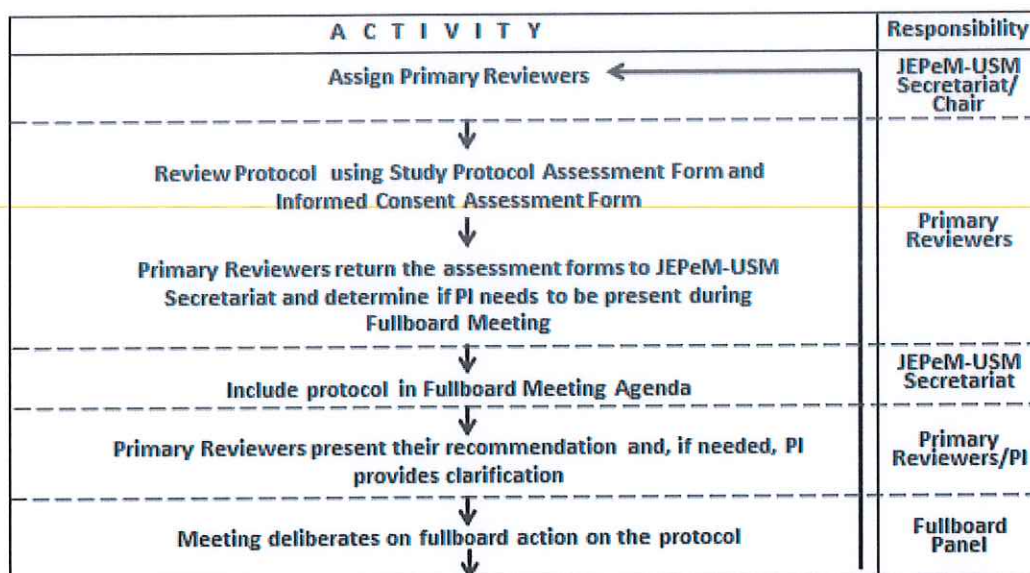
- 7.1.2.1 Research which involves clinical trial of new drug/treatment/procedure
- 7.1.2.2 Study which involves randomized control trial and intervention study
- 7.1.2.3 Research which involves questionnaires or survey to vulnerable groups
- 7.1.2.4 Genetic and/or Genomic Studies
- 7.1.2.5 Any other study not fulfilling expedited review criteria

7.1.3 Exemption: Researches (monitoring program, consumer satisfaction, program evaluation and surveillance study) that do not involve human participants or subjects, human materials, or human data are technically exempt from review, but will be subject to expedited review at the level of the Chairperson. The criteria are:

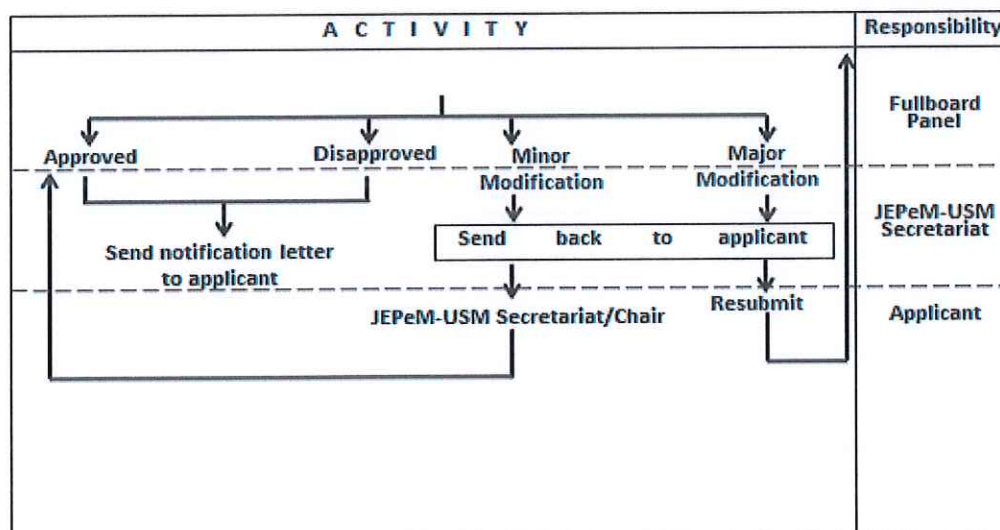
- Protocols that do not involve human participants or identifiable human tissue, biological samples
- Systematic reviews and meta-analysis
- Audits/evaluations organised by management for the purpose of quality improvement within the institution **only**.
- Protocols that involve the use of publicly available data or information.
- **Full Board Review (Flowchart 6)**

7.2 Full Board Review (Flowchart 6)

Flowchart 6 SOP II – Fullboard Review



Flowchart 6 SOP II – Fullboard Review

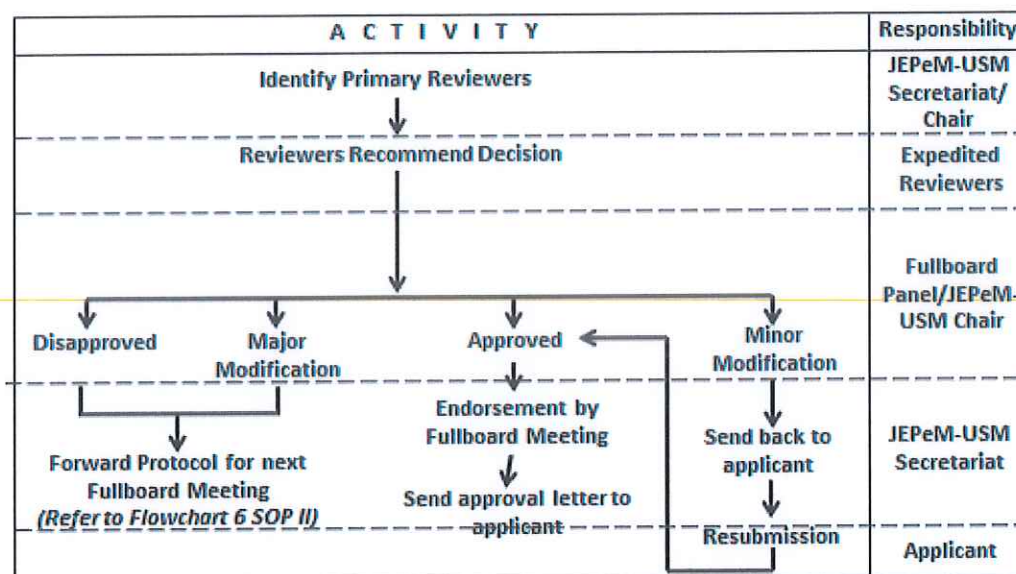


- 7.2.1 The quorum for the full board meeting is seven (7) members including at least one (1) of the non-institutional members or one (1) non-life science member and one (1) female member. The Panel Chair will ensure that reviewers or members who are expert in the area specific to the protocol are present during the board meeting.
- 7.2.2 The report of primary reviewers will be presented in the full board meeting where decision is deliberated.
- 7.2.3 For decisions on resubmissions and other post approval submissions, JEPeM- USM may request information or clarification from the PI when the need arises.
- 7.2.4 In the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the JEPeM-USM. For approved applications, all requests for withdrawal will be discussed during full board meetings. Upon approval of request, study protocol will be archived as stipulated in **SOP IV-8: ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

7.3 Expedited Review (Flowchart 7)

- 7.3.1. For expedited review study protocols, the primary reviewer accomplishes **JEPeM-USM FORM 2(C): Study Protocol Assessment Form** and **JEPeM-USM FORM 2(D): Informed Consent Assessment Form**, and returns them to the Secretariat Staff within **ten (10) working days** from the date of the transmittal letter to the primary reviewers.
- 7.3.2. 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: **APPROVAL, MINOR MODIFICATIONS; PI Not Invited for Presentation, MINOR MODIFICATIONS; PI Invited for Presentation, MAJOR MODIFICATIONS; PI Invited for Presentation during Full board meeting, OR DISAPPROVAL.**
- 7.3.3. Expedited study protocols that are marking as major modifications and disapproved by any primary reviewer are referred for full board review.

Flowchart 7 SOP II – Expedited Review



8. Full Board Meeting Workflow

8.1 Workflow

ACTIVITY	RESPONSIBILITY
Set regular meeting schedule ↓	Chairperson/Secretary
Distribute meeting agenda ↓	Secretariat Staff
Prepare meeting materials ↓	Secretariat Staff
Determine quorum ↓	Secretariat Staff
Call the meeting to order ↓	Chairperson
Confirm/Certify quorum ↓	Secretary
Read and approve the minutes ↓	Chairperson/Members
Declare conflict of interest ↓	Chairperson/Members

Review initial study protocol submissions and resubmissions ↓	Chairperson/ Members/Secretary
Conduct PI presentation ↓	Chairperson/Members/ Secretary
Review post-approval submissions ↓	Chairperson/Memb ers/Secretary
Review reports of expedited review ↓	Chairperson/ Members/Secretary
Adjourn meeting ↓	Chairperson
Collect, store, and dispose meeting materials	Secretariat Staff

8.2 DETAILED INSTRUCTIONS

8.2.1 Regular meeting schedule

- 8.2.1.1 Regular meeting includes full board meeting and expedited meeting as necessary to process the protocols with reasonable amount of time.
- 8.2.1.1 The JEPeM-USM secretariat must set regular meeting
- 8.2.1.2 The Secretariat Staff confirms venue reservation for the scheduled meeting date and time **five (5) working days** before the meeting.
- 8.2.1.3 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.
- 8.2.1.4 Regular meeting can be in the form of regular face-to-face or virtual meeting.

8.2.2 Distribution of the Meeting Agenda

- 8.2.2.1 The Secretariat Staff distributes the **JEPeM-USM FORM 2(G): MEETING AGENDA** together with the related study protocols or study protocol synopses to meeting attendees (members, invited PIs, independent consultants, and others) at least **three (3) calendar days** before the date of the meeting.
- 8.2.2.2 The Secretariat Staff sends meeting reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone at least within **three (3) calendar days** before the meeting, upon which time the members confirm their attendance. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in their formal invitation to attend the meeting.

8.3 Preparation of Members' Meeting Folders, Study Protocols, and Study Protocol- Related Submissions Scheduled for Review

- 8.3.1 The Secretariat Staff makes copies of the approved Minutes [JEPeM-USM FORM 4(A): **FORMAT OF THE MINUTES OF THE MEETING**] of the previous meeting, for all members attending the meeting. For details regarding preparation of the Minutes refer to **SOP IV-4: MINUTES OF THE MEETING**.
- 8.3.2 The Secretariat Staff distributes the folders containing meeting materials such as agenda and minutes at the start of the meeting. The folders are collected afterwards and shredded.

8.4 Determination of Quorum

- 8.4.1 Quorum is defined as the presence of at least seven (7) members described as follows:
- 8.4.1.1 Expert members
 - 8.4.1.2 At least one (1) member with interest in Non-science
 - 8.4.1.3 At least one (1) member independent of the institution (who can be represented by the non-scientific member as the case may be)
 - 8.4.1.4 Representation of both female and male members
- 8.4.2 In studies involving children, a pediatrician or child development expert should be present.
- 8.4.3 A field expert related to protocols being reviewed will be invited as the need arises.
- 8.4.4 In case of anticipated lack of quorum, the JEPeM-USM Secretary will search for a suitable corresponding alternate from any other JEPeM-USM Members.
- 8.4.5 On the appointed meeting time, the Secretary determines quorum viability and informs the Chairperson to indicate readiness to call the meeting to order.

8.5 Calling the Meeting to Order and Completion of Required Procedures Prior to Review Proper

- 8.5.1. The Chairperson calls the meeting to order upon confirmation of quorum by the Secretary. In the absence of Chairperson, a Deputy Chairperson/Panel Chair or designated member will be appointed. When a panel chair is not available, only other panel chairs can replace the panel chair. When there is COI during the session, the panel chair may request a senior member to stand in.
- 8.5.2. The JEPeM-USM also allows, at the discretion of the Chairperson, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe JEPeM-USM meetings. These guests and observers (non-members) attending any JEPeM-USM Panel Meeting is required to sign a **CONFIDENTIALITY AGREEMENT FOR GUESTS/OBSERVERS [JEPeM-USM FORM 2(I): 2019]**.

- 8.5.3. The Secretariat Staff documents the proceedings of the meeting under the supervision of the Secretary, as soon as the meeting is called to order by the Chairperson, 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. For details regarding preparation of the **Minutes of the Meeting**, refer to SOP IV-4: MINUTES OF THE MEETING.
- 8.5.4. The Chairperson calls upon the Secretary to formally confirm quorum by citing the attendance requirements.
- 8.5.5. The Chairperson 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 Secretary. The Chairperson instructs the members who declared COI to recuse themselves from the deliberation of the respective study protocol for which the COI declaration was made.
- 8.5.6. The Chairperson presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The Chairperson then declares approval of the Minutes of the previous meeting.
- 8.5.7. The Chairperson 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.

8.6 *Discussion of Initial Study Protocol Submissions and Resubmissions*

- 8.6.1. Full board review of study protocol and study protocol-related submissions typically includes review of the following in sequence:
- Initial Study Protocol Submissions
 - Resubmission or Study Protocols for Modification
 - PI presentation
 - Withdrawal of Study Protocol Applications
 - Study Protocol Amendment Applications previously approved in full board review process
 - Final Reports
 - Serious Adverse Event Reports
 - Site Visit Reports
 - Study Protocol Noncompliance (Deviation or Violation) Reports

- Early Study Termination Applications
- Queries from Various Stakeholders

- 8.6.2. The Chairperson may allow some modifications of the sequence of review in an exigency circumstances. For example, if a presentation is included in the agenda, the panel may opt to move this up in the review sequence.
- 8.6.3. The Chairperson instructs the member who had previously declared conflict of interest (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 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.
- 8.6.4. For initial review, the Chairperson calls the primary reviewers to present findings on respective study protocols based on study protocol assessment points specified in **JEPeM-USM FORM 2(C): STUDY PROTOCOL ASSESSMENT FORM** and elements detailed in **JEPeM-USM FORM 2(D): INFORMED CONSENT ASSESSMENT FORM**.
- 8.6.5. The scientific primary reviewer is instructed to review mainly on scientific soundness and its impact on human subject protection, while the non- scientific primary reviewer is instructed to review the informed consent process and all related forms as well as its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies.
- 8.6.6. The Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.
- 8.6.7. For protocol with decision minor modification/major modification/resubmissions, the timelines for the PI to submit the revised protocol is within **forty (40) working days** from the date of communication letter to the PI. The Chairperson/panel chair may call the primary reviewers if necessary to present findings on the response of the PI to the previous recommendations of the panel summarized in **JEPeM-USM FORM 2(H) 2019: REVIEW OF RESUBMITTED STUDY PROTOCOL**. If the researcher require more time for correction, the researcher should formally request an extension to the Chair/Panel Chair. If the researcher fails to request an extension but proceeds to submit the protocol, the submission will be processed as initial review.
- 8.6.8. In case of unavailability of the primary reviewers to attend the meeting, said members are required to forward the completed assessment forms to the Secretariat Staff **three (3) calendar days** before the meeting. The findings summarized therein will be presented by the Chairperson or his designee when the study protocol is deliberated on. Whenever feasible, the said members should be available for various means of communications in case of clarification needed.

8.6.9. For decision on both initial study protocol submission and resubmission, the Chairperson calls for any of the following actions:

- **Approved**
- **Minor Modification, which can be expedited at the level of the Secretary and Chairperson**
 - If the modifications are minor in a sense of grammatical
 - corrections or other minor corrections not involving the methodology, the decision of minor correction will be made with review at the secretary/chairperson level.
- **Minor Modification, which require review and recommendation by the Primary Reviewers**
 - If the modifications are deemed minor but involve methodology, the revised version will be reviewed by the assigned primary reviewers.
- **Major Modification, which require full board deliberation**
 - If the modifications include major parts of methodology or major ethical issues to be addressed, revised versions of projects with this decision will be sent to the primary reviewer and will be tabled again in the full board meeting.
- **Not Approve /Resubmission**
 - The project has major flaws and needs resubmission. These re-submitted projects will be handled as if they were new projects for initial review.

8.6.10. If in case one primary reviewer is absent and/ or has not submitted his/her review, discussion of the study protocol may still proceed at the discretion of the Chairperson. If the Chairperson feels that the present member's composition does not have the expertise to proceed with the review, the discussion of the study protocol may be deferred until the next meeting. Also, the Board may request comments or presentation interview from the PI.

8.6.11. The JEPeM-USM allows investigators and other resource persons (such as an Independent Consultant commissioned by the JEPeM-USM or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the part of the board 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).

8.7 Conduct of PI Interview

8.7.1. The committee member's conducts, if any, interviews with PIs and/or study team members whose submissions raise ethical issues that are better addressed by the PI himself/herself.

- 8.7.2. The Secretariat Staff sends **JEPeM-USM FORM 4(D): LETTER FOR CLARIFICATORY INTERVIEW** to PIs called for interview. PIs may also request an interview with the committee members by formally expressing their intention in writing.
- 8.7.4. Clarificatory interviews may be conducted in person or through tele/video conference or skype application.
- 8.7.5. The Chairperson calls for action depending on the type of submission (See **SOP II-7.1**). Decisions are based on the members' assessment of the PI's response to their queries.

8.8. Discussion of Post-Approval Submissions

- 8.8.1. The Chairperson/Panel Chair presents, if any, **STUDY PROTOCOL AMENDMENT SUBMISSION FORMS [JEPeM-USM FORM 3(A)]** that entail major amendments substantially affecting previous risk-benefit assessment on the study protocol. For details on classification of amendments and subsequent processing requirements, refer to **SOP III-4.1: STUDY PROTOCOL AMENDMENT**. The Chairperson/Panel Chair calls for any of the following actions:
- *Approval*
 - *Minor modification to the study protocol amendment, subject to expedited review at the level of the Chairperson*
 - *Major modification to the study protocol amendment, subject to full board review*
 - *Disapproval*
- 8.8.2. The Chairperson/Panel Chair presents, if any, submissions for Continuing Review of study protocols previously approved through full board and any **CONTINUING REVIEW APPLICATION FORMS [JEPeM-USM FORM 3(B)]** ascertained to have altered previous risk-benefit assessment on the study protocol. For details on how continuing review applications are processed, refer to **SOP III-4.2: CONTINUING REVIEW APPLICATION**. The Chairperson/Panel Chair calls for any of the following actions:
- *Uphold original approval with no further action*
 - *Request information*
 - *Recommend further action*
- 8.8.3. The Chairperson/Panel Chair presents, if any, **FINAL REPORT FORMS [JEPeM-USM FORM 3(C)]** of completed studies. For details on how Final Reports are processed, refer to **SOP III-4.3: FINAL REPORTS**. The Chairperson/Panel Chair calls on the Members to deliberate on the summary of findings and related ethical issues, including post-study management of study participants, and decide on panel action such as:

- *Approve*
- *Request information*
- *Recommend further action*

8.8.4. The Chairperson/Panel Chair presents, if any, reports on Serious Adverse Events (SAEs) and reports of the Serious Adverse Events Subcommittee. If there are serious issues related to the report of the Serious Adverse Events Subcommittee, the Chair of the above committee should attend the meeting to present analysis and to recommend action to the panel. For details on how Serious Adverse Events Reports are processed, refer to **SOP III-5: SERIOUS ADVERSE EVENT REPORTS**. The Chairperson/Panel Chair calls on the Members to deliberate on the recommendations of the SAE Subcommittee Chair and decide on panel action such as:

- *Uphold original approval with no further action*
- *Recommend further action*
- *Forward to SAE Subcommittee*

8.8.5. The Chairperson/Panel Chair presents, if any, reports on **SITE VISITS [JEPeM- USM FORM 3(F): CHECKLIST FOR SITE VISIT]**. For details on how Site Visits are conducted and reported, refer to **SOP III-6: SITE VISIT**. The Chairperson/Panel Chair calls on the Members to recommend any of the following actions:

- *Uphold original approval with no further action*
- *Request information*
- *Recommend further action*

8.8.6. The Chairperson/Panel Chair presents, if any, **STUDY PROTOCOL NON- COMPLIANCE (DEVIATION OR VIOLATION) REPORTS [JEPeM-USM FORM 3(D)]** of study protocols previously approved through full board. Noncompliance may be in the form of noncompliance with post-approval requirements. For details on how Study Protocol Noncompliance (Deviation or Violation) Records are processed, refer to **SOP III-4.4: STUDY PROTOCOL NON-COMPLIANCE (DEVIATION OR VIOLATION) REPORT**. The Chairperson/Panel Chair calls on the Members to recommend any of the following actions:

- *Uphold original approval with no further action*
- *Request information*
- *Recommend further action*
- *Forward to SAE Subcommittee*

8.8.7. The Chairperson/Panel Chair presents, if any, **EARLY STUDY TERMINATION APPLICATION FORMS [JEPeM-USM FORM 3(E)]** of study protocols previously approved through full board. For details on how Early Study Termination Applications are processed, refer to **SOP III-4.5: EARLY STUDY TERMINATION APPLICATION**. The Chairperson/Panel Chair calls on the Members to recommend any of the following actions:

- *Approval*
- *Request information*
- *Recommend further action*

8.8.8. The Chairperson/Panel Chair presents, if any, **QUERIES OR COMPLAINTS [JEPeM-USM FORM 3(I)]**. For details on how queries are processed, refer to **SOP III-4.6: QUERIES OR COMPLAINTS**. The Chairperson/Panel Chair calls on the Members to recommend any of the following actions:

- *Uphold original approval with no further action*
- *Request information*
- *Recommend further action*

8.9. Review of Results of Expedited Review

- 8.9.1. The Chairperson/Panel Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review.
- 8.9.2. The submissions are reported in the same sequence as full board review with similar corresponding actions (see **SOP II-7.1**).
- 8.9.3. In the event that there is no meeting for the month, the Secretariat Staff will notify all members regarding the results of expedited review through email/courier for information or comments.

8.10. Adjournment of the Meeting

- 8.10.1. Before closing the meeting, the Chairperson/Panel Chair calls for any non- study protocol matters that need attention or action, as the need arises.
- 8.10.2. With no further matters for discussion, the Chairperson/Panel Chair formally adjourns the meeting, with the time noted by the Secretariat Staff who is documenting the meeting.

8.11. Collection and Storage or Disposal of Meeting Materials

- 8.11.1. The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND JEPeM-USM DOCUMENTS**.
- 8.11.2. The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and

SOP IV-8 ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES. For online recordings and meeting material, this will be stored electronically.

8.12 Decision Making

- 8.12.1 A member shall withdraw from decision making procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson/panel chair prior to the review of the application and recorded in the minutes.
- 8.12.2 Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants, with the exception of JEPeM-USM's Secretariat.
- 8.12.3 Decision only made at meetings where there is enough quorum present (refer to 4.9. Full board meeting)
- 8.12.4 All decisions should be taken in meetings and not by circulation of research proposals.
- 8.12.5 Decisions will be taken by consensus after discussions and whenever needed voting will be done.
- 8.12.6 Decision may be approval, minor revision, major revision or rejection of the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- 8.12.7 For rejected proposal, appeal can be made to the Chairperson within **forty (40) working days** after the meeting. Appeal can be made by written clarification to the Chairperson. The decision shall be determined by the Chairperson.

8.13 Minute of Meeting

The minute of the meeting shall be provisionally approved by the JEPeM-USM Chairperson/Deputy Chairperson/Panel Chair within **twenty (20) calendar days** after the respective meeting. The researcher(s) shall be notified the decision of the application preferably within **three (3) calendar days** after the minute of the meeting provisionally approved by the Chairperson/Deputy Chairperson/Panel Chair. Provisional approval of the minute is subject to final approval by the next full board meeting.

8.14 Letter of Approval

The Letter of Approval is signed by the Chairperson/Deputy Chairperson/Panel Chair and contains the following;

- The date of meeting
- The members present at the meeting
- The documents reviewed by the committee
- The decision of the committee
- The reasons for disapproval (for disapproved protocol)
- The names of investigators approved to do the research
- The venue where the research to be conducted
- The expected date of commencement and duration of the research

The committee will monitor the progress of the project. Procedures for monitoring are designated in SOP III (Post-Approval Review).

9. Special Meeting Workflow

ACTIVITY	RESPONSIBILITY
Prepare for conduct of special meeting ↓	Secretariat Staff
Conduct special meeting ↓	Chairperson/ panel chair Secretary/Members
Collect, store, and dispose meeting materials	Secretariat Staff

DETAILED INSTRUCTIONS

9.1. Preparation for Conduct of Special Meeting

- 9.1.1. A special meeting may be called by the Chairperson or a member of the JEPeM-USM.
- 9.1.2. The decision to call a special meeting is based on the following criteria:
 - 9.1.2.1. Urgent issues (if delay will affect or have impact on the public benefit, national economy, image of institution etc.)
 - 9.2.1.2. Occurrence of unexpected serious adverse events
 - Any matter of grave outcome
 - Other similar situations

- 9.1.3. The Secretariat informs the JEPeM-USM members, including the invite persons, about the special meeting.

9.2. Conduct of Special Meeting

- 9.2.1. Quorum is defined as the presence of at least five (5) members described as follows:

- At least one scientific member
- A non-scientific member
- At least one non-institutional member
- A member/or invited guest with expertise on the item to be discussed

- 9.2.2. A special meeting may be conducted among the members through tele/video conference or skype application.

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

9.3 Collection and Storage or Disposal of Meeting Materials

- 9.3.1 The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND JEPeM-USM DOCUMENTS.**

- 9.3.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and **SOP IV-8 ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES**

10. Clarification Meeting Workflow

ACTIVITY	RESPONSIBILITY
Prepare for conduct of clarification meeting ↓	Secretariat Staff
Conduct clarification meeting ↓	Chairperson/ panel chair Secretary/Members
Collect, store, and dispose meeting materials	Secretariat Staff

DETAILED INSTRUCTIONS

10.1 *Preparation for Conduct of Clarification Meeting*

- 10.1.1 A clarification meeting may be called by the Chairperson/Panel Chair of the JEPeM-USM whenever further clarification is required.
- 10.1.2 The Secretariat informs the JEPeM-USM members, including the invited persons, about the clarification meeting.

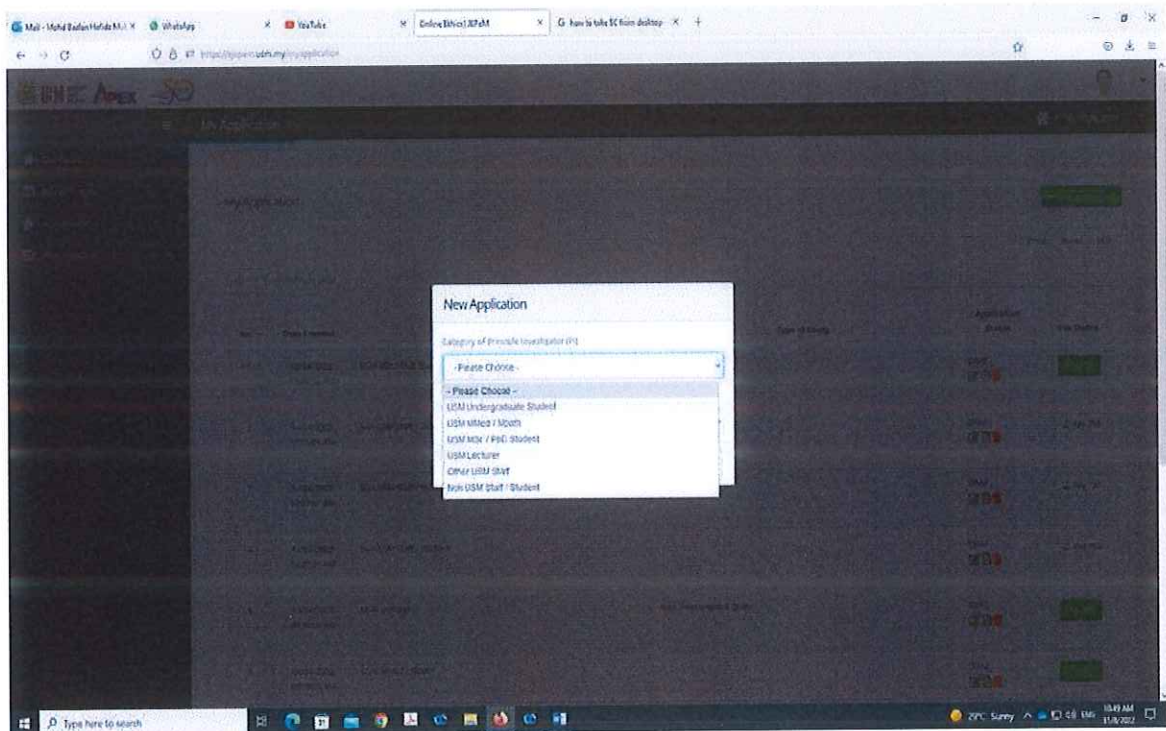
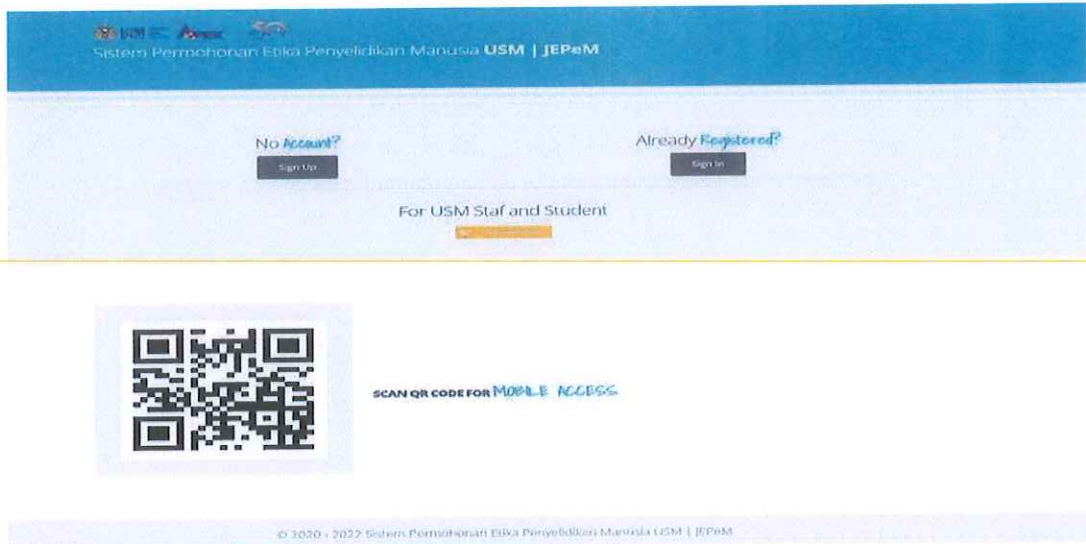
10.2 *Conduct of Clarification Meeting*

- 10.2.1 Minimum quorum is chair/panel chair, one staff secretariat and two members in the relevant field
- 10.2.2 A clarification meeting may be conducted among the members through tele/video conference or skype application.
- 10.2.3 The nature of the meeting will be stated by the secretariat staff in the beginning of the meeting

10.3 *Collection and Storage or Disposal of Meeting Materials*

- 10.3.1 The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND JEPeM-USM DOCUMENTS.**
- 10.3.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and **SOP IV-8 ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

Appendix A: Online submission Package



My Application My Application / Registration

INSTRUCTION
Applicant must complete all 6 sections below.
1 Registration, 2 Approval by other ethics committee, 3 Team Members, 4 Details, 5 Upload Document, 6 Confirmation

Registration & Application Form

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 CONFIRMATION 6

Study title:

Type of Submission:

Type of Study:

Study Duration (months):

Study site (where the study will be conducted):
PLEASE LIST ALL SITES

Type Of Study Site: Funding:

[Save & Next](#)

✓ Request Successful! Record saved.

Approval by other ethics committee

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 CONFIRMATION 6

Approval by other ethics committee:

Name of Institutional Review Board or Ethics Review Committee:

Approval Letter: [+ Upload](#)

Date of Ethics Approval Start to Expired: to

[Previous](#) [Save & Next](#)

✓ Request Successful Record Saved

[+ Add Investigators](#)

Team Members

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 CONFIRMATION 6

Print Excel PDF

10 records per page

No	Name	Role in study	CV	Option
No data available in table				

Previous Next

← Previous Save & Next →

INSTRUCTION
Full Research Proposal is compulsory. Other separate files is optional.
A list of the uploaded files is available at the end of this section.
Please refer to [RESEARCH PROPOSAL TEMPLATE FOR MEDICAL AND HEALTH SCIENCES](#)

Details - Template Protocol Medical & Health Sciences

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 CONFIRMATION 6

Research Proposal for Medical Sciences and Related Disciplines Document(s)

No	Type of Document	File	#
1	Full Research Proposal	+ Upload	
2	Introduction	+ Upload	
3	Problem statement & Study rationale	+ Upload	
4	Research Question(s)	+ Upload	
5	Objective	+ Upload	
6	Literature review	+ Upload	

My Application [My Application](#) / [Template Protocol Medical & Health Sciences](#) / [Upload Section](#)

1 Registration, **2** Approval by other ethics committee, **3** Team Members, **4** Details, **5** Upload Document, **6** Confirmation

Upload Section

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 SECTION 6

1. If your project requires written informed consent, please click [HERE](#) for the template of the IS and CF-3. If your project does not require written informed consent, please click button "Skip to Confirmation" below to proceed.

[Skip to Confirmation →](#)

3. If your project involves Hospital Universiti Sains Malaysia (HUSM), please click [HERE](#) for Borang Persempurnaan Penggunaan Data Pesakit, Perkhidmatan Mahal & Lain-lain di HUSM (Borang GBB HUSM).

4. Other requirements: Endorsement forms are required to be submitted EXCEPT for industry Sponsored Research (ISR). Endorsement form also can be downloaded [HERE](#).

Type of Document:

No	Type of Document	File	#
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[← Previous](#) [SUBMIT APPLICATION](#)

Confirmation

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 SECTION 6

Final Instructions:
APeP file of your proposal has been created by the system. Please review the [APeP file](#) and make correction in the application form where needed.

If your project involves Hospital Universiti Sains Malaysia (HUSM) please click [HERE](#) for Borang Persempurnaan Penggunaan Data Pesakit, Perkhidmatan Mahal & Lain-lain di HUSM (Borang GBB HUSM).

The last page of that file is the endorsement form to be filled by your research dean or head of department. Endorsement form also can be downloaded [HERE](#).

Please upload the endorsement form by clicking form below.

Type of Document:

No	Type of Document	File	#
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[← Previous](#) [SUBMIT APPLICATION](#)