Standard Operating Procedures
II. PROTOCOL REVIEW

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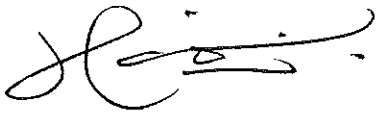
Approved by:	 Professor Dato' Dr. Faisal Rafiq Mahamd Adikan Vice Chancellor, Universiti Sains Malaysia
Approval Date:	22/9/2022

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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), 2(J) 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

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.

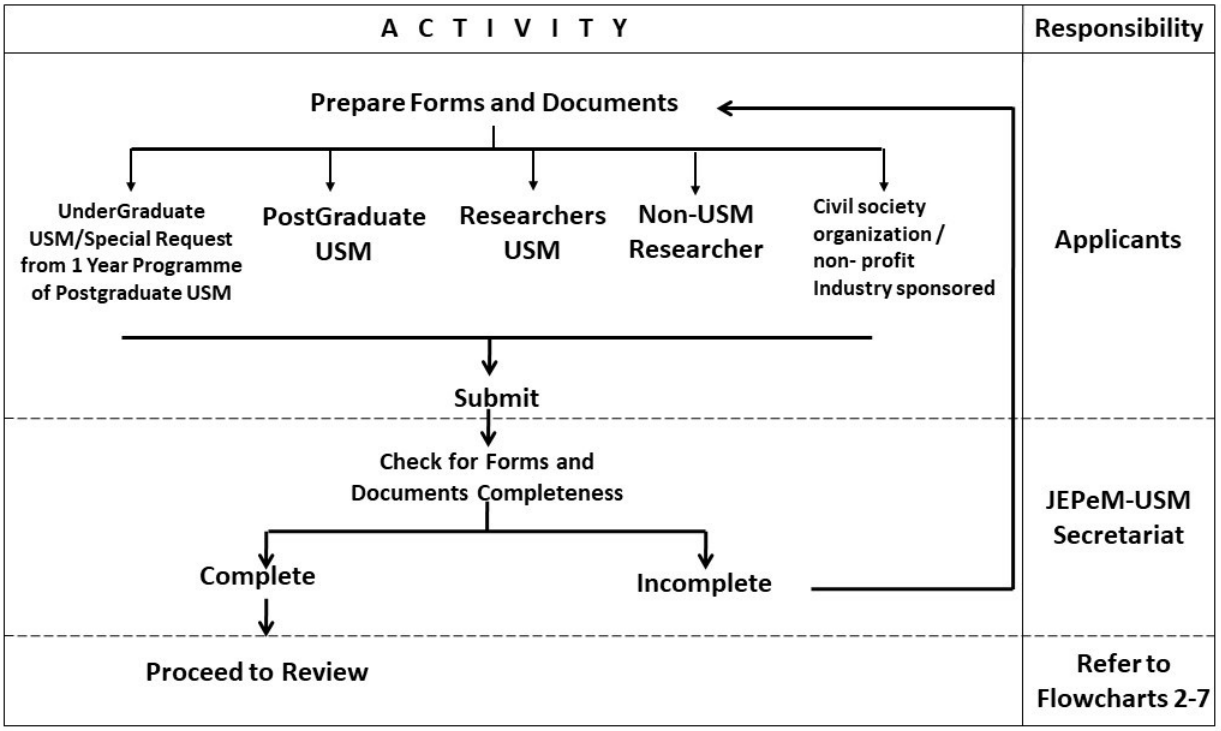
Assigned reviewers are responsible for systematically review the study protocol, write their comments after each item listed in the study protocol and informed consent assessment forms, include consideration of relevant guidelines when doing the review, and submit review comments to the JEPeM-USM Secretariat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

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)

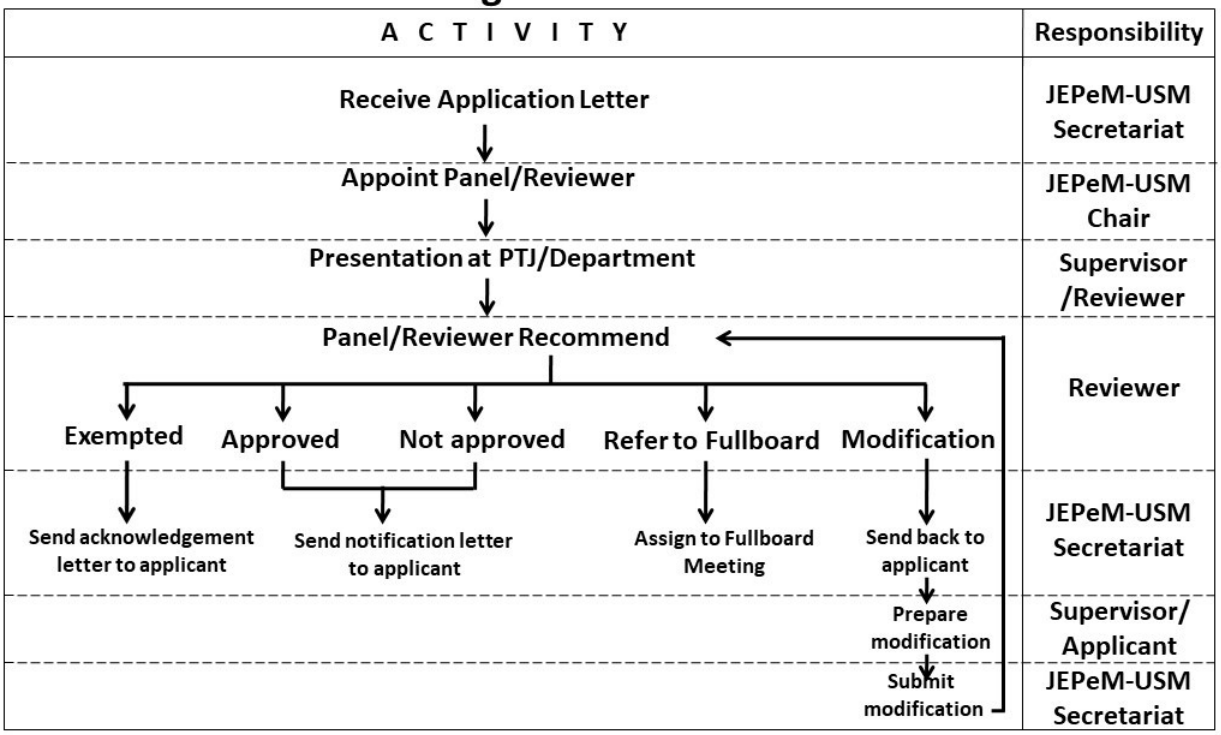
4.1.2 Postgraduate USM (Flowcharts 3a and 3b)

4.1.3 Researchers USM (Flowchart 4)

4.1.4 Non-USM Researchers/civil society organization/Industry sponsored (Flowchart 5)

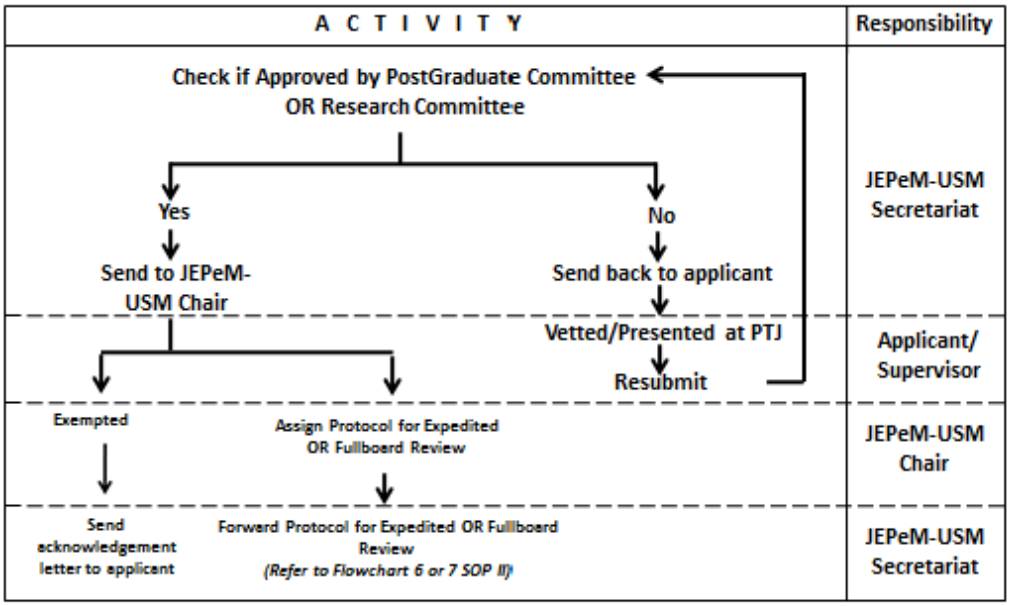
Flow Chart 2

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

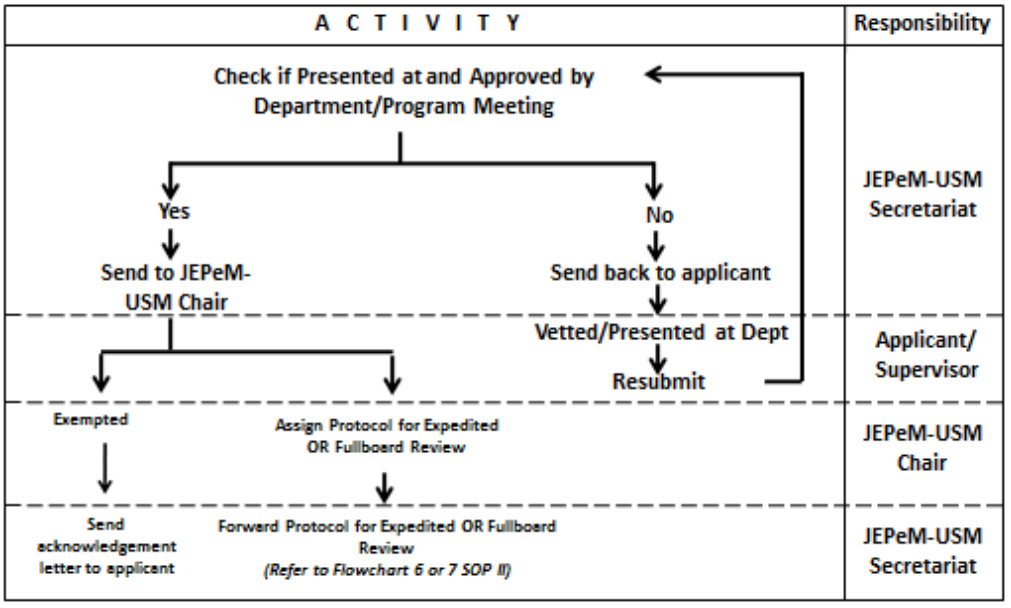


Flow Chart 3

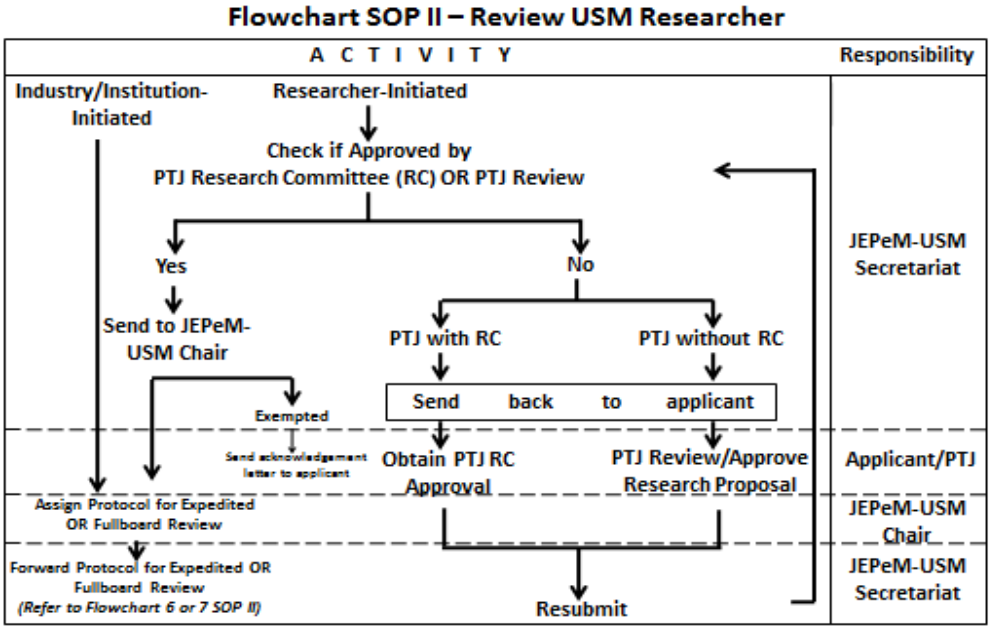
Flowchart 3 (a) – Review PostGraduate (By Research) USM



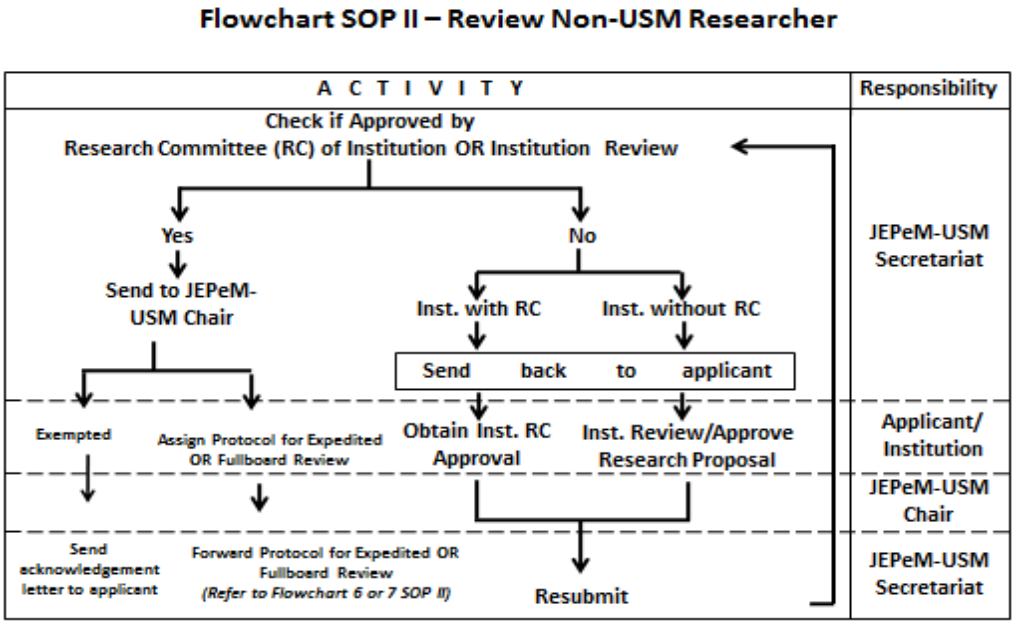
Flowchart 3b SOP II – Review PostGraduate (Coursework/Mixed Mode) USM



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.

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 FORM2(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 need to accomplish the acknowledgement receipt in **JEPeM-USM FORM 2(J): TRANSMITTAL LETTER TO THE PRIMARY REVIEWER.**

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 Reviewers have Two (2) working days to decline a review

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

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

6.3.11 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

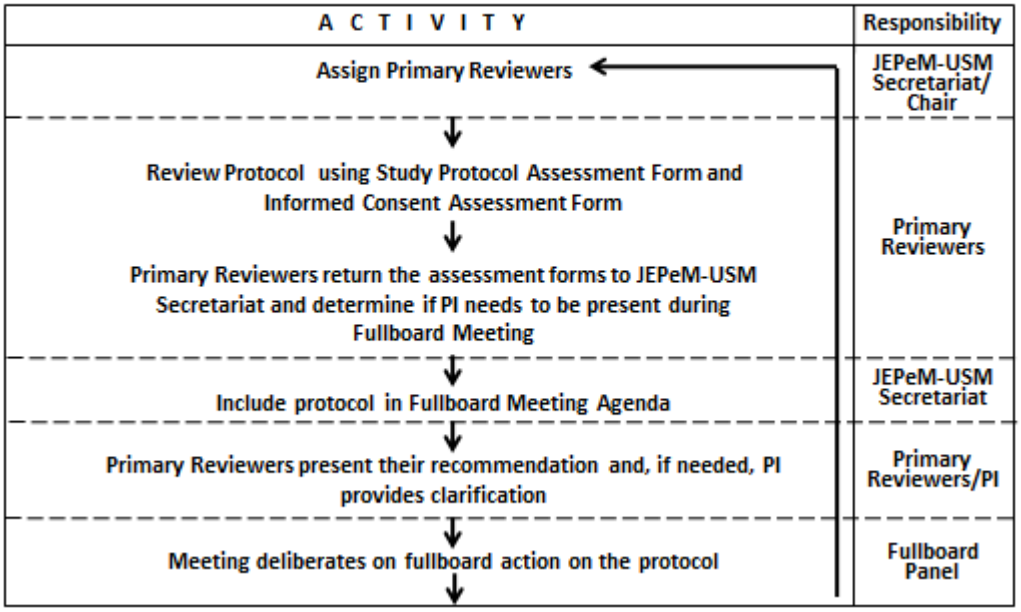
7.1.2.5 Any other study not fulfilling expedited review criteria

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:

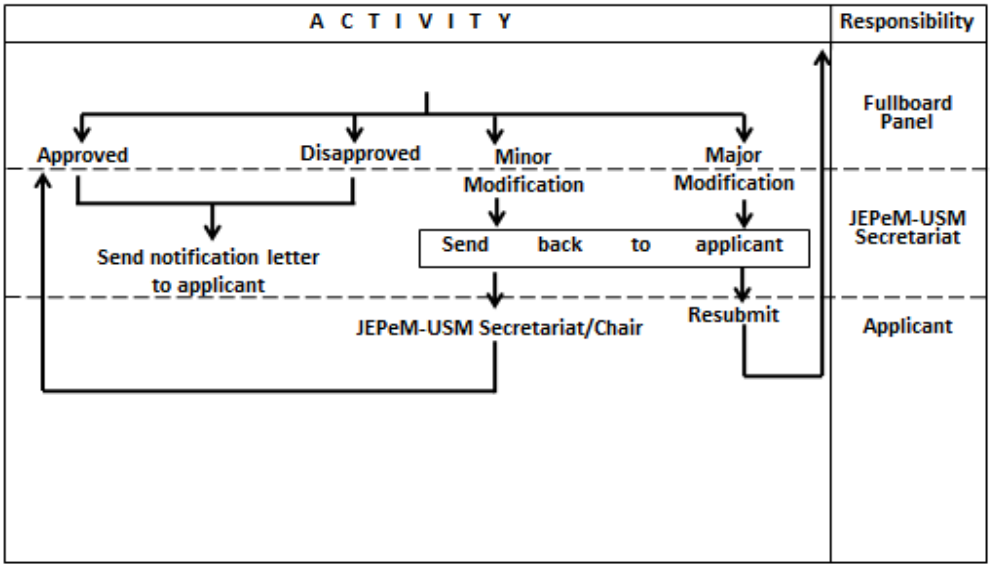
- Protocols that do not involve human participants or identifiable human tissue, biological samples
- Systematic reviews and meta-analysis
- Audits/evaluations organised by management for the purpose of quality improvement within the institution **only**.
- Protocols that involve the use of publicly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

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.

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.**

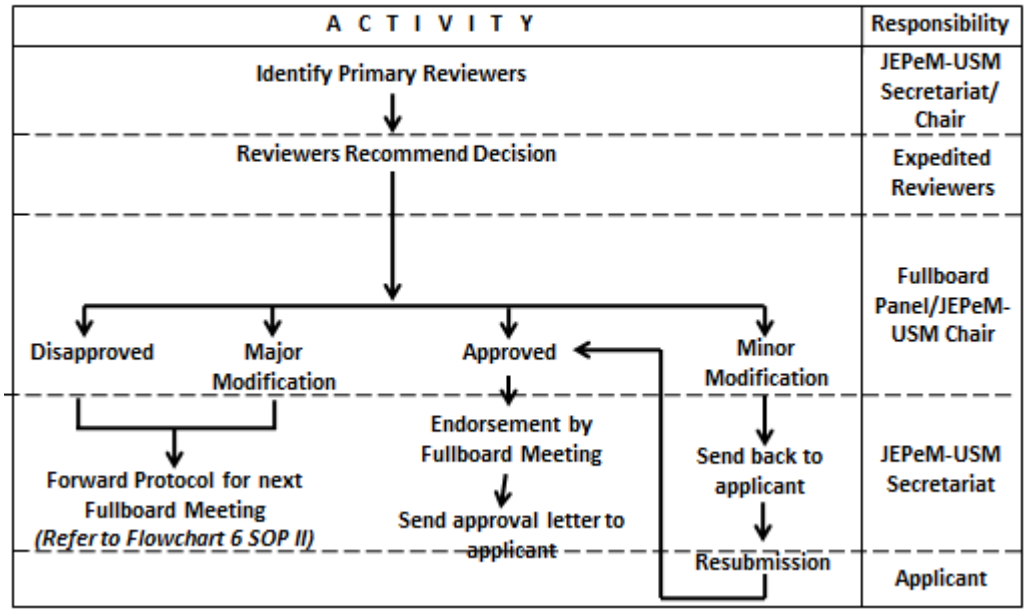
7.3 Expedited Review (Flowchart 7)

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 review of minor modification/major modification/resubmissions, the timelines for the investigators to resubmit the revised protocol is within **forty (40) working days** from the date of communication letter to the PI. The Chairperson calls the primary reviewers 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.**

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 ORVIOLATION) 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

8.15 Follow Up and Monitoring

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 invited 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.

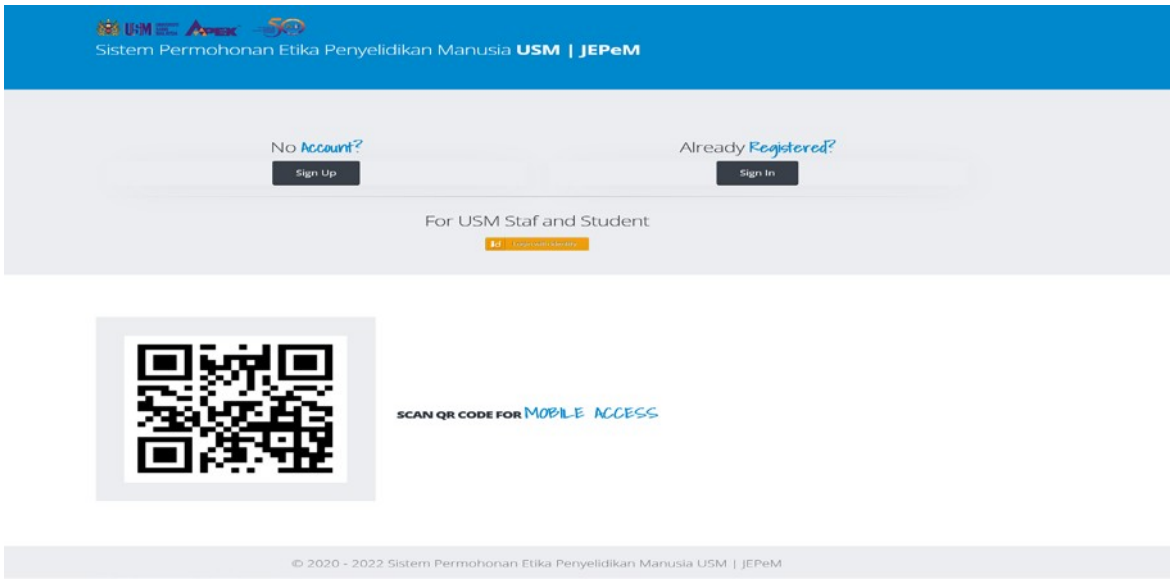
9.2.3. The meeting is conducted in the same sequence as full board review with similar corresponding actions.

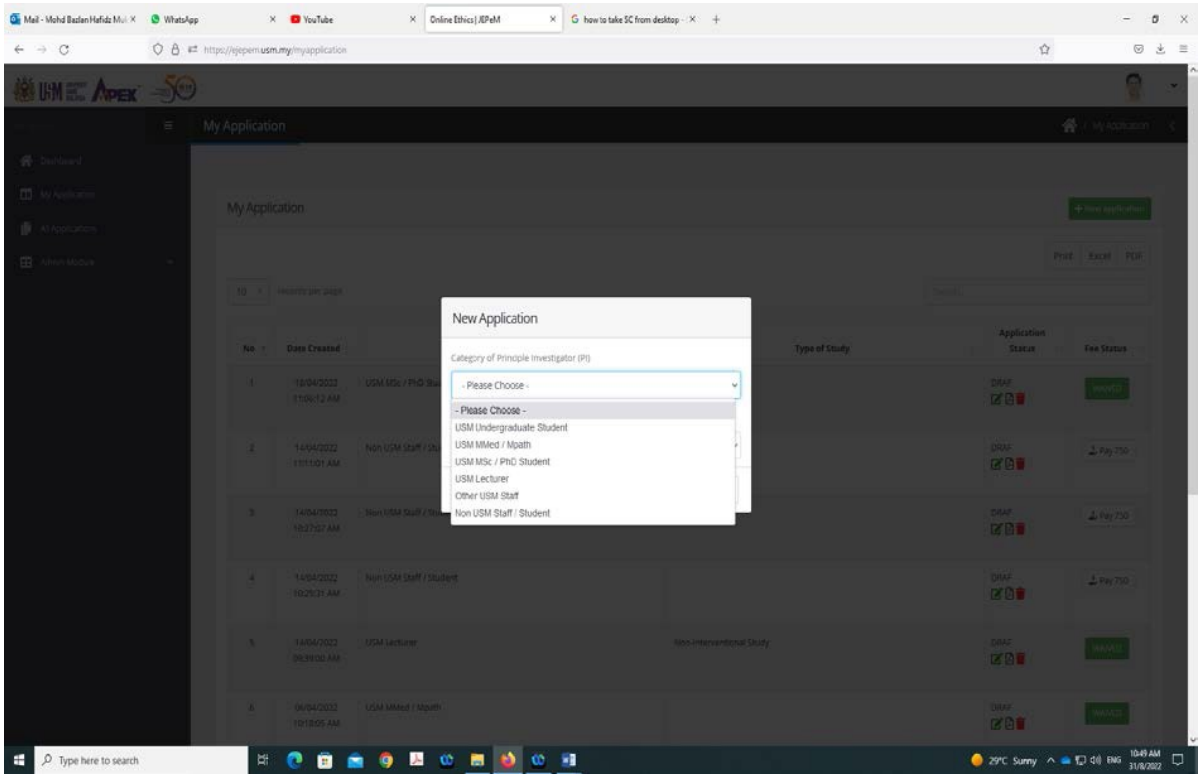
9.3 *Collection and Storage or Disposal of Meeting Materials*

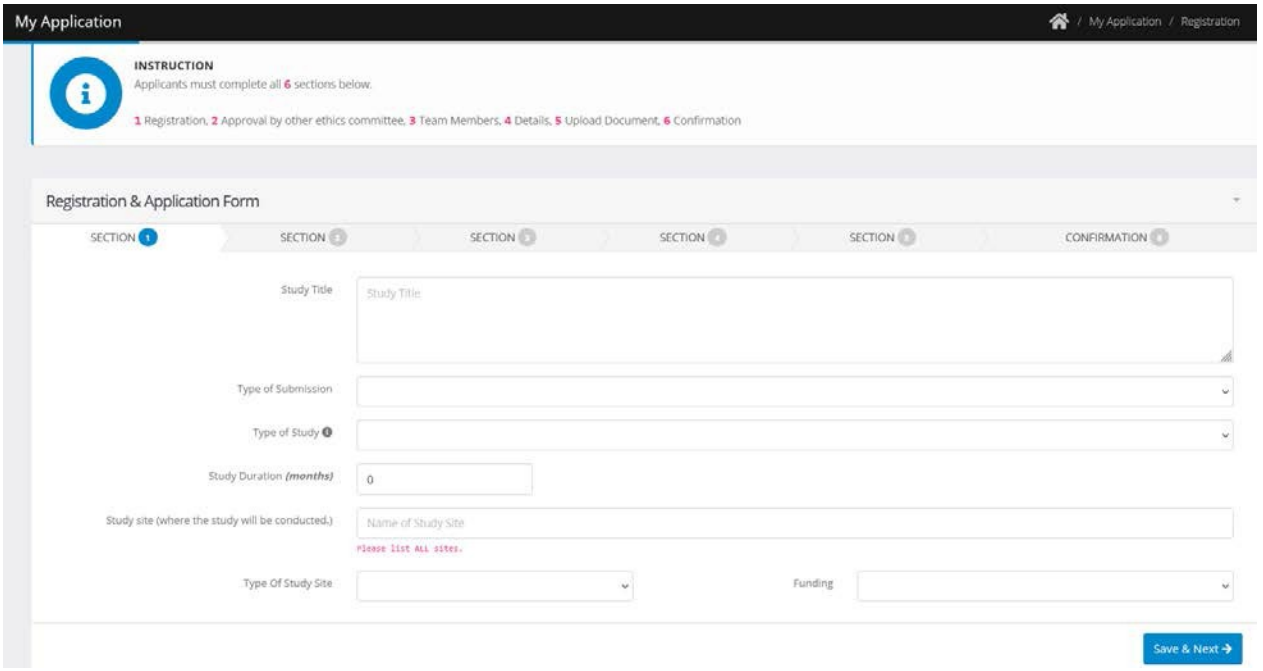
9.3.1 The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND JEPeM-USM DOCUMENTS**.

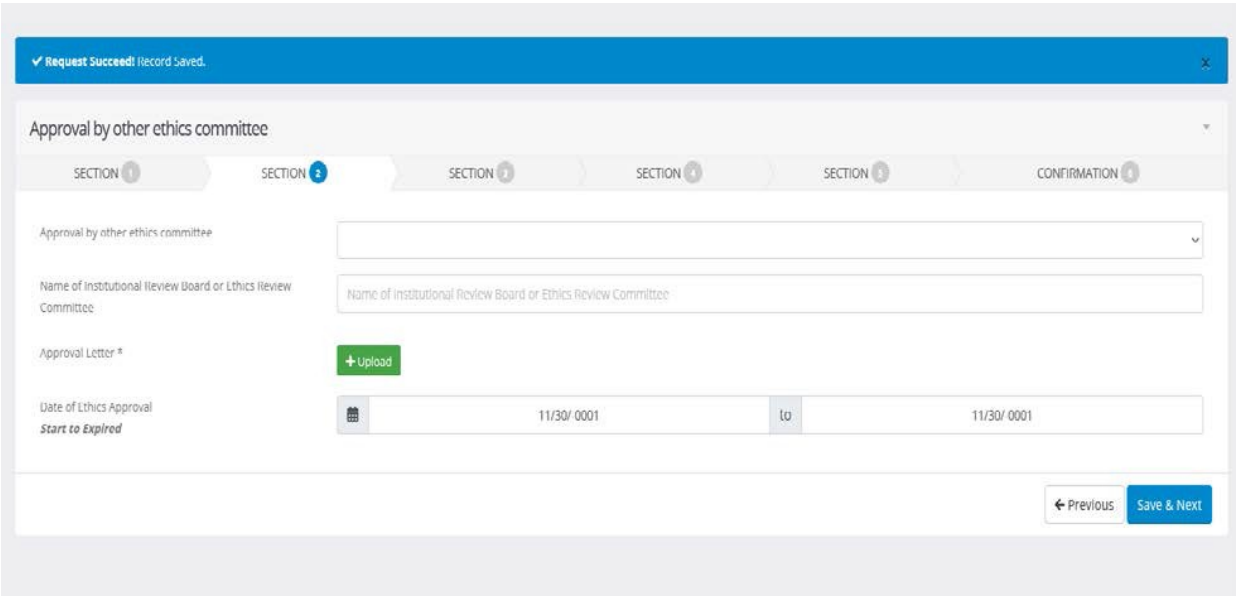
9.3.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and **SOP IV-8 ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

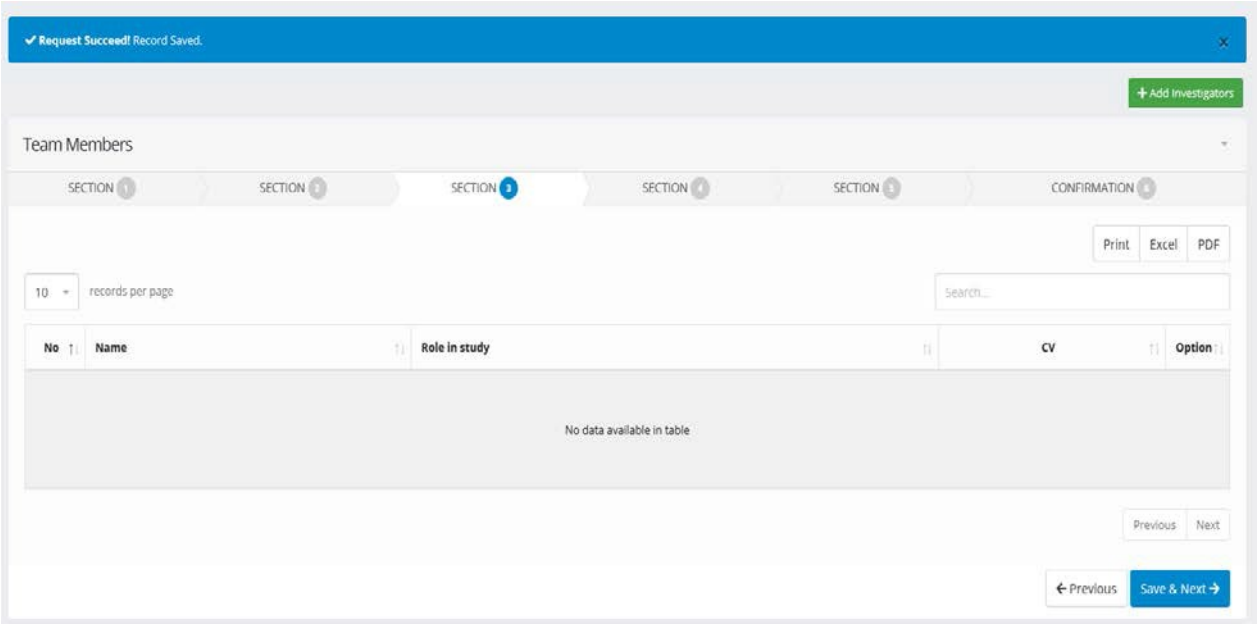
Appendix A: Online submission Package

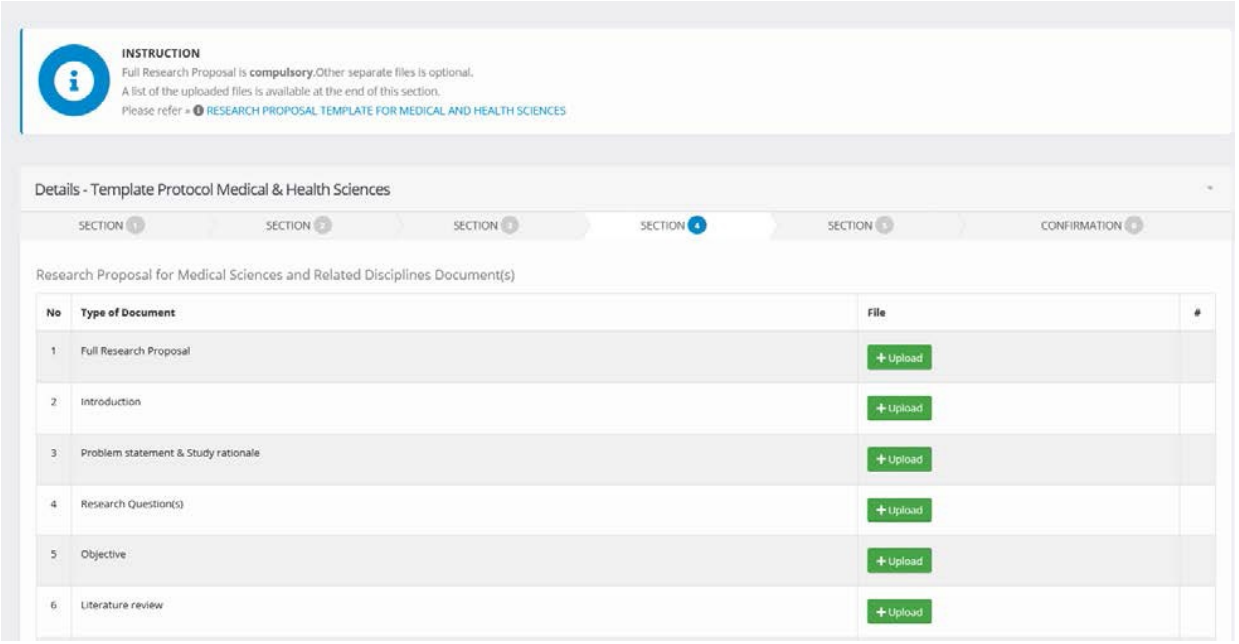


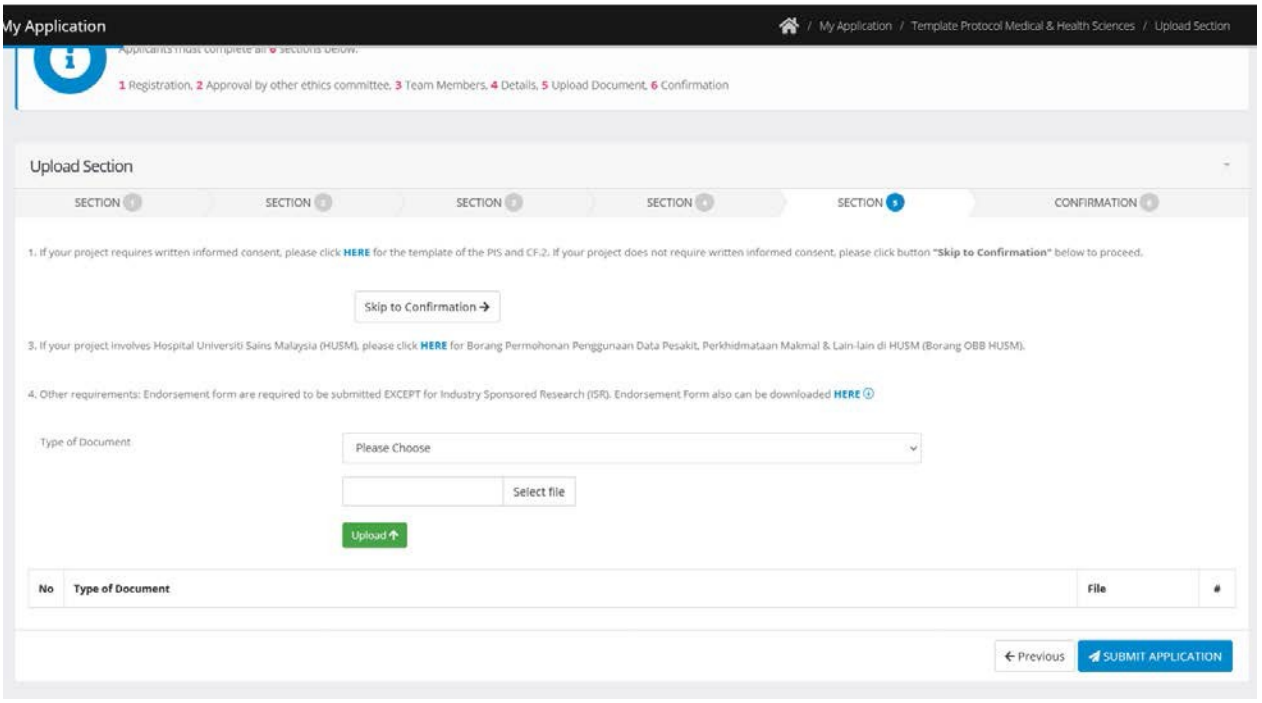


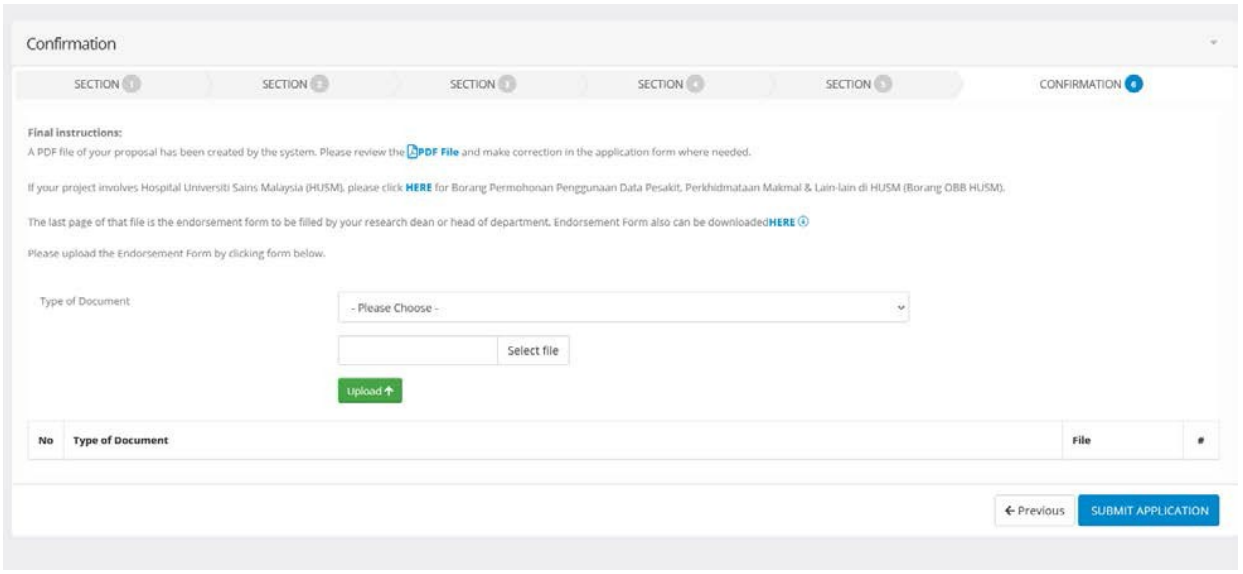

My Application
/ My Application / Registration
INSTRUCTION
Applicants must complete all 6 sections below.
1 Registration, 2 Approval by other ethics committee, 3 Team Members, 4 Details, 5 Upload Document, 6 Confirmation
Registration & Application Form
SECTION 1
SECTION 2
SECTION 3
SECTION 4
SECTION 5
CONFIRMATION 6
Study Title
Study Title
Type of Submission
Type of Study
Study Duration (months)
0
Study site (where the study will be conducted.)
Name of Study Site
*Please list ALL sites.
Type Of Study Site
Funding
Save & Next


Request Succeed! 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
Name of Institutional Review Board or Ethics Review Committee
Approval Letter *
+Upload
Date of Ethics Approval
Start to Expired
11/30/ 0001
to
11/30/ 0001
Previous
Save & Next


Request Succeed! 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
Search...
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 » 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
SECTION
SECTION
SECTION
SECTION
CONFIRMATION
1. If your project requires written informed consent, please click HERE for the template of the PIS and CF.2. 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 Permohonan Penggunaan Data Pesakit, Perkhidmataan Makmal & Lain-lain di HUSM (Borang OBB HUSM).
4. Other requirements: Endorsement form are required to be submitted EXCEPT for Industry Sponsored Research (ISR). Endorsement Form also can be downloaded HERE
Type of Document
Please Choose
Select file
Upload
No
Type of Document
File
#
Previous
SUBMIT APPLICATION


Confirmation
SECTION
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SECTION
CONFIRMATION
Final instructions:
A PDF file of your proposal has been created by the system. Please review the PDF File and make correction in the application form where needed.
If your project involves Hospital Universiti Sains Malaysia (HUSM), please click HERE for Borang Permohonan Penggunaan Data Pesakit, Perkhidmataan Makmal & Lain-lain di HUSM (Borang OBB 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 downloadedHERE
Please upload the Endorsement Form by clicking form below.
Type of Document
- Please Choose -
Select file
Upload
No
Type of Document
File
#
Previous
SUBMIT APPLICATION

For JEPeM-USM Secretariat Purposes Only	
Protocol Code	**USM/JEPeM/**
Is the submission complete?	☐ **Yes** ☐ **No**
Completeness Verified By	
Date of Verification	

REVIEW CHECKLIST (To be filled by Principal Investigator [PI])

STUDY PROTOCOL INFORMATION

Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date:	

Please note that:

-Applicants are required to submit three (3) set of copies including one (1) original copy. For the Industry Sponsored Research (ISR), ten (10) set of copies including one (1) original copy are required.

-For the Undergraduate Student Application, submission of this form is not required.

Compulsory documents (Please tick [√] in the boxes if it is available in the submission packages).

- ☐ **JEPeM-USM FORM 2(A)2022 Review Checklist**
- ☐ **JEPeM-USM FORM 2(B)2022 Registration and Application Form**
- ☐ **JEPeM-USM FORM 2(C)2022 Study Protocol Assessment Form**
- ☐ **JEPeM-USM FORM 2(D)2022 Informed Consent Assessment Form**
- ☐ **Full study protocol**
  - ☐ Introduction & Study Background
  - ☐ Literature review
  - ☐ Justification of Study
  - ☐ Research Objectives
  - ☐ Methodology
    a. Inclusion criteria
    b. Exclusion criteria
    c. Recruitment
    d. Research Tools/Tools materials (Questionnaire/Proforma/Data collection sheet)
  - ☐ Ethical Consideration
  - ☐ Proposed Data Analysis and Expected Result
  - ☐ References
  - ☐ Flow Chart & Gantt Chart
- ☐ **Study subject/participant information sheet – Refer to JEPeM USM template**
- ☐ **Study subject/participant informed consent form – Refer to JEPeM USM template**
- ☐ **Brief [1 page] CVs of researchers – Refer to JEPeM USM template**
- ☐ **Attendance sheet**

Study-specific Documents (if applicable)

- ☐ Research tool materials
- ☐ Previous ethical review approvals/clearances
- ☐ Assent form
- ☐ Notification Letter to related governmental office for studies with specific needs

For Clinical Trial

- ☐ Investigator's Brochure
- ☐ Basic Product Information Document
- ☐ Letter of indemnity/ insurance coverage
- ☐ Assent form in local language
- ☐ Good Clinical Practice (GCP) Certificate of PI, Co-I
- ☐ Recruitment advertisements
- ☐ Material Transfer Agreement
- ☐ Memorandum of Agreement
- ☐ Clinical Trial Agreement (Draft document is acceptable)
- ☐ Financial Contract (Draft document is acceptable)
- ☐ Statement of Publication Rights
- ☐ Site Resources Checklist for Clinical Trial Outside USM By USM Personnel **[JEPeM-USM FORM 2(E)2022]**
- ☐ Site Resources Checklist for Clinical Trial Outside USM By non-USM Personnel **[JEPeM-USM FORM 2(F)2022]**
- ☐ Clearance or permit from respective regulatory authorities
- ☐ Proof of fee payment

***Additional notes (if any) with regards to this application – to be filled by the Secretariat Staff:**

Untuk kegunaan Setiausaha JEPeM-USM sahaja:

(For Secretary of JEPeM-USM Purposes Only)

Permohonan ini akan dibincangkan dalam mesyuarat:

(This application will be discussed in the meeting of):

[ ] Expedited Review Meeting

Penilai Pertama (Primary Reviewers):

1.

2.

3.

[ ] Full Board Review Meeting

Penilai Pertama (Primary Reviewers):

1.

2.

3.

_____

Tandatangan Pengerusi/Timbalan Pengerusi
(Signature of Chairperson/Deputy Chairperson)

Tarikh:
(Date)

For JEPeM-USM Secretariat Purposes Only	
Protocol Code	**USM/JEPeM/**

Registration and Application Form

For Initial Review and Resubmission

(Please fill in or tick whenever appropriate)

Please print in A4 size paper

SECTION I: APPLICATION INFORMATION	
1. Study Title	
2. Type of Submission	☐ Initial Review ☐ Resubmission [*Version and date of version must be inserted as a document footer for all resubmissions*]
3. Date of Submission:	
4. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrates ☐ Others (indicate):
5. Type of study:	☐ Specify based on FOR/SEO : _____ **(http://mrdcs.mastic.gov.my/assets/downloads/v6.pdf)** ☐ Clinical Trial Phase I ☐ Clinical Trial Phase II ☐ Clinical Trial Phase III ☐ Clinical Trial Phase IV (Post Marketing Surveillance) ☐ Whole-Genome Study (submit appropriate Informed Consent Form for Whole-Genome Study) ☐ Interventional Study ☐ Non-interventional Study ☐ Combination of Interventional and Non-Interventional Study ☐ Others, please indicate:

6. Category of Principal Investigators ***Please refer to Sections II-IV***	☐ 6.1 USM Lecturer/Researcher *(This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT)* ☐ 6.2 USM Post/Graduate Student (Master/Doctorate) *(This category requires completion of SECTION IIA: SUPERVISOR APPROVAL and SECTION IIB: SCIENTIFIC REVIEW APPROVAL)* ☐ 6.3 Other USM staffs (Nurse, Administrative Staff, etc.) *(This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT)* ☐ 6.4 Non-USM *(This category requires completion of SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW below)* ☐ 6.5 Others, please specify:
7. Purpose of study	☐ Academic requirement (Thesis, Dissertation, Training Requirement) ☐ Independent research work ☐ Multi-institutional or multi-country collaboration ☐ Others (indicate):
8. Study Duration	_____ months
9. Involvement of special populations or vulnerable groups	☐ Not involving special populations or vulnerable groups ☐ Children (under 18) ☐ Indigenous People/people ☐ Elderly ☐ People on welfare/social assistance ☐ Poor and unemployed ☐ Homeless persons ☐ Refugees or displaced persons ☐ Prison Inmate/inmate or other institutionalized individuals ☐ Subordinates ☐ Patients currently under your care ☐ Patients in emergency care ☐ Patients with incurable diseases ☐ Others (indicate): _____
10. Hosting Institution (University/School/Department/Unit/Center where the PI is employed)	**NAME OF HOSTING INSTITUTION :** **TYPE OF HOSTING INSTITUTION** ☐ USM ☐ Non-USM Malaysia ☐ Non-USM outside Malaysia
11. Study site (where the	**NAME OF STUDY SITE :**

study will be conducted. Please list ALL sites)	**TYPE OF STUDY SITE** ☐ USM School/Department/Unit/Center/Premise/Hospital ☐ Non-USM with local IRB/ERB/ERC ☐ Non-USM without local IRB**/**ERB/ERC
12. Status of Funding	☐ In process ☐ Approved ☐ No funding (skip 13 and 14)
13. Funding :	**NAME OF FUNDING/GRANT :**
	TYPE OF FUNDING AGENCY ☐ USM ☐ Investigator (Self-funding) ☐ Malaysian Government agency/office/entity ☐ External Government agency/office/entity ☐ Multilateral Agency (UN agencies and other intergovernmental agencies) ☐ Private company or Non-governmental organization (NGO) ☐ Others (indicate): _____
14. Amount of Study Budget	MYR _____ (Other currency, please specify: _____)
15. Previous ethics approval or clearance issued by other sites	☐ Name of Institutional Review Board or Ethics Review Committee: _____ Date of ethics approval: _____ Date of expiration of ethics approval: _____ ☐ In process ☐ Not applicable
16. Principal Investigator	**Name** <Title, Name, Surname> : _____
	IC/Passport Number : _____
	Address <Institutional Address> : _____ _____ _____
	Office Phone : _____
	Facsimile : _____
	Hand phone : _____
	Email : _____

17. *Other Ongoing studies by the Principal Investigator (please add additional row/sheet if necessary)*	☐ Title: JEPeM-USM Code (if applicable):	
	☐ Title: JEPeM-USM Code (if applicable):	
	☐ Not applicable	
18. Declaration of Conflict of Interest of PI (refer to the JEPeM USM website)	☐ I have no conflict of interest in any form	
	☐ I have personal/family/financial interest in the results of the study	
	NATURE:	
	☐ I have proprietary interest in the research (patent, trademark, copyright, licensing)	
	NATURE:	
19. Other investigators (Co-researchers; including study supervisors) with corresponding task description *(please add additional rows/sheet if necessary)*	Co-Investigator: Task description:	
	Co-Investigator: Task description:	
20. Submitted by:		
	Designation	
21. PI signature		

Please print your relevant section only

SECTION IIA: SUPERVISOR APPROVAL (for categories 6.2) **This section should be signed by the appointed Supervisor of the Principal Investigator (Postgraduate Student) that approved the study**	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
I confirm that I have read this Application and that the research will be implemented under my supervision in accordance with the conditions of approval by the JEPeM-USM. I also confirm that the Principal Investigator is a student under my supervision.	
Supervisor Name	
Signature and Stamp:	Date of Signature:

SECTION IIB: SCIENTIFIC REVIEW APPROVAL (for categories 6.1, 6.2 and 6.3) *This section should be signed by the Chair of Research Committee (for categories 6.1 and 6.3) or the Chair of Postgraduate Committee/Head of Department (for category 6.2) that reviewed the scientific merit of the study and issued the appropriate approval. Alternatively, results of Scientific Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.*	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
I confirm that the (RESEARCH/POSTGRADUATE COMMITTEE/HEAD OF DEPARTMENT) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling method, sample size, Inclusion/exclusion/ withdrawal criteria; data collection, processing, storage and data analysis plan including statistical design/framework, as applicable.	
Issuing committee/office:	
Head of committee/office:	
Signature and Stamp:	Date of Signature:

SECTION III: PTJ ENDORSEMENT (for categories 6.1 and 6.3) *This section should be signed by the head of PTJ (administrative authority legally empowered to sign on behalf the PTJ such as Dean of School, Director of Hospital, Director of Center/Institute and the like) of the Principal Investigator. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.***	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
I confirm that I have read this Application and that the research will be implemented under the supervision of this School/Department/Institution in accordance with the conditions of approval by the JEPeM-USM. I also confirm that the Principal Investigator is a staff in this institution.	
Issuing PTJ:	
Head of PTJ:	
Signature and Stamp:	Date of Signature:

SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW (for category 6.4 and 6.5) *This section should be completed by the signatory official who represents the institution that has supervisory role on the research site. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.***	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
This is to certify that the **<NAME OF RESEARCH SITE>:** 1) Has no local Institutional Review Board/ Ethics Review Committee; and 2) Authorizes and acknowledges the JEPeM-USM, located at the Division of Research & Innovation, USM Health Campus, Kubang Kerian, Kelantan to perform the ethical review of the abovementioned study protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits. OR 3) Had received permission from USM authority to conduct research within USM premises (attach permission letter)	
Name of Hosting Institution	
Address of Hosting Institution	
Signatory Official	
Position of Official	

Signature and Stamp	Date of Signature:

JEPeM USM Code:	USM/JEPeM/

Request Form for Under Graduate/Special Request from 1 Year Programme of Post Graduate USM Review

Please print in A4 size paper

SECTION I: Program Information		
1. Program name		
2. Name of School/Centre		
3. Name of the Program coordinator **Office no.** **Mobile no.** **e-mail add:**		
SECTION II: Students Information		
1. No. of students project to be reviewed		
2. Year / semester of study		
3. Academic requirement of study	☐ Program Project ☐ Elective ☐ Industrial training ☐ Others (please indicate):	
4. Project timeline *The timeline of the project to be initiated and completed based on the program schedule*	Date of initiation Date of completion	
5. Requested by:	<Title, Name>	
	Designation	
6. Signature & Official stamp		

*** THREE (3) COPIES of the research proposal, participant information sheet and consent form & Curriculum Vitae (CV) [if applicable] and all relevant forms and questionnaire MUST be submitted to the JEPeM USM secretariat at least 10 working days before the schedule of the review.**

**** For the students who will conduct an interventional study/study on vulnerable population which falls under category of Full Board Review, please submit together:**

A. Review Checklist
B. Research Proposal
B. Study Protocol Assessment Form (Interventional Study/Non-Interventional Study)
C. Participant Information Sheet and Consent Form
D. Participant Information Sheet and Consent Assessment Form (Interventional Study/Non-Interventional Study)
E. Curriculum Vitae (CV) of researchers

Please fill in SECTION II A for each student's project

SECTION IIA: SUPERVISOR APPROVAL *This section should be signed by the appointed Supervisor of the Principal Investigator (Undergraduate Student) that approved the study*	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
I confirm that I have read this Application and that the research will be implemented under my supervision in accordance with the conditions of approval by the JEPeM-USM. I also confirm that the Principal Investigator is a student under my supervision.	
Supervisor Name	
Signature:	Date of Signature:

For JEPeM-USM Secretariat Purposes Only	
Request received date:	
Reviewer:	
Expedited review schedule:	
Date:	
Time:	
Venue:	

Verified by:

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

STUDY PROTOCOL ASSESSMENT FORM FOR INTERVENTIONAL STUDY

PROTOCOL CODE:
USM/JEPeM/

Study Protocol Title:				
Principal Investigator:				
Study Protocol Submission Date:				
Undergraduate application exempted	**To be filled by the PI**			**To be filled by Reviewer**
Indicate if the study protocol contains the specified assessment point			**Page**	**REVIEWER'S COMMENTS**
	YES	**N/A**		
Study Justification				
Literature review				
Objectives *General and specific objectives*				
Research design				
Sample size estimation				
Sampling method				
Inclusion and exclusion criteria				
Vulnerability of the subject/participant *How it is handled*				
Recruitment of subject/participant & informed consent seeking *Method of inviting participants e.g: Advertisement*				
Assent form requirement ***Under 7 years old: No assent. Complete Parental Consent.*** ***7-under 12 years old: Verbal Assent*** ***12-under 15 years old: Assent Form*** ***15-under 18 years old: Co-sign informed consent form with parents***				
Randomization, matching, blinding				
Suitability of study area/study location				
Validity of research instruments				

Method of intervention *What to be done to the subjects, possible risk & benefit*				
Control group				
Potential risk to subject/participant e.g. psychological distress				
Direct & indirect benefit to subject/participant				
Data/Specimen handling				
Duration of participant involvement				
Withdrawal criteria				
Proposed data analysis				
Incentive,compensation &/or reimbursement				
Declaration of conflict of interest				
Handling privacy & confidentiality issue				
Community sensitivities & benefits				
PI & Co-Investigator qualification (include in GCP Certificate)				
Collaborative study terms of reference				

RECOMMENDATION

- ☐ **APPROVED**
- ☐ **MINOR MODIFICATIONS; PI not to be invited**
- ☐ **MINOR MODIFICATIONS; PI to be invited**
- ☐ **MAJOR MODIFICATIONS**
- ☐ **DISAPPROVED**

JUSTIFICATION FOR RECOMMENDATION

PRIMARY REVIEWER	Signature	
Date:	Name	
SECRETARY	Signature	
Date:	Name	

STUDY PROTOCOL ASSESSMENT FORM FOR NON-INTERVENTIONAL STUDY

PROTOCOL CODE:
USM/JEPeM/

Study Protocol Title:				
Principal Investigator:				
Study Protocol Submission Date:				
Undergraduate application exempted	**To be filled by the PI**			**To be filled by Reviewer**
Indicate if the study protocol contains the specified assessment point			**Page**	**REVIEWER'S COMMENTS**
	YES	**N/A**		
Justification for study and literature review *Summarize the available knowledge and important knowledge gap to justify the scientific merit of the study proposed*				
Objectives *General and specific objectives*				
Research design				
Sample size estimation				
Sampling method				
Inclusion and exclusion criteria				
Vulnerability of the subject/participant *How it is handled*				
Recruitment of subject/participant & informed consent seeking *Method of inviting participants eg: Advertisement*				
Assent form requirement ***Under 7 years old: No assent. Complete Parental Consent.*** ***7-under 12 years old: Verbal Assent*** ***12-under 15 years old: Assent Form*** ***15-under 18 years old: Co-sign informed consent form with parents***				
Study location				
Research instrument				
Data collection method ***What to be done to the subjects/participants, possible risk & benefit***				

Duration of participant involvement				
Proposed data analysis				
Declaration of conflict of interest				
Handling privacy & confidentiality issue				
Community sensitivities & benefits				
Incentives/honorarium/ compensation				
Collaborative study terms of reference e.g. Intellectual property, etc.				

RECOMMENDATION

- ☐ **APPROVED**
- ☐ **MINOR MODIFICATIONS; PI not to be invited**
- ☐ **MINOR MODIFICATIONS; PI to be invited**
- ☐ **MAJOR MODIFICATIONS**
- ☐ **DISAPPROVED**

JUSTIFICATION FOR RECOMMENDATION

PRIMARY REVIEWER	Signature
Date:	Name
SECRETARY	Signature
Date:	Name

PROTOCOL CODE:
USM/JEPeM/

Participant Information Sheet and Informed Consent Assessment Form for Interventional Study

Study Protocol Title:				
Principal Investigator:				
Study Protocol Submission Date:				
	To be filled by the PI			**To be filled by JEPeM-USM Reviewers**
Essential Elements **(as applicable to the study)**	Indicate if the ICF has the specified element		Page and paragraph where element is found	**REVIEWER'S COMMENTS**
	YES	**N/A**		
List of all investigators involved				
Research title				
Introduction of study scope				
Statement that the study involves experimental or interventional research				
Procedure of intervention				
Approximate number of participants				
Description of the study purpose				
Eligibility criteria to participate				
Statement that subject/participant will be randomized into groups				
Statement that the participation may be terminated if certain circumstances and reasons occur				
Study procedures that will be done and responsibilities of subjects/participants				
Expected duration of participation				
Foreseeable or potential risks to subject/ participant including control group subject/ participant and risks to immediate family members e.g. psychological distress				
Potential risk to the subjects in control group including the use of placebo				
Expected or absence of direct benefit to participants				
Community sensitivities and expected benefits to the community or to society, or contributions to scientific knowledge				
Alternative procedures/management/treatment available to participant				
Statement that participation is voluntary, and right to withdraw anytime without penalty or loss of benefit or participation can be terminated				
Statement that the JEPeM-USM Review Panel and regulatory authorities may review study data				

Assurance of confidentiality unless required by law				
Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant				
Compensation or insurance or treatment entitlements of the participant in case of study-related injury				
Compensation for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries				
Anticipated payment, to the participant (monetary or non monetary)				
Anticipated expenses, if any, to the participant in the course of the study				
Specimen/data handling including storage and destruction of specimen/data at the end of the study				
Statement of possible future use, affirming participant's right to refuse future storage and use of collected specimen/data				
Plans to develop commercial products and whether the participant will receive monetary or other benefit from such development				
Statement describing feedback of study finding				
Statement describing extent of participant's right to access his/her records				
Description of post-study access to the study product or intervention after proven safe and effective				
Sponsor, institutional affiliation of the investigators, and nature and sources of funds				
Statement whether the investigator is serving only as an investigator or as both investigator and the participant's service provider				
Information of person(s) to contact in the study team for further information or in case of study related event				
Statement on the approval by and contact of the secretary of the JEPeM-USM				
Appropriate language versions				

RECOMMENDATION

- ☐ APPROVED
- ☐ MINOR MODIFICATIONS
- ☐ MAJOR MODIFICATIONS
- ☐ DISAPPROVED

Reasons:

REVIEWER

Signature _____

Date:

Name

SECRETARY

Signature _____

Date: Name

PROTOCOL CODE:
USM/JEPeM/

Participant Information Sheet and Informed Consent Assessment Form for Non-Interventional Study

Study Protocol Title:				
Principal Investigator:				
Study Protocol Submission Date:				
	To be filled by the PI			**To be filled by JEPeM-USM Reviewers**
Essential Elements **(as applicable to the study)**	Indicate if the ICF has the specified element		Page and paragraph where element is found	**REVIEWER'S COMMENTS**
	YES	**N/A**		
List of all investigators involved				
Research title				
Statement that the participant involves research				
Introduce study scope				
Approximate number of participants				
Description of the study purpose				
Eligibility criteria to participate				
Study procedures and expectation				
Expected duration of participation				
Foreseeable or potential risks (including psychological, physical and emotional)				
Expected or absence of direct benefit to participants				
Community sensitivities and expected benefits to the community or to society, or contributions to scientific knowledge				
Statement that the JEPeM-USM Review Panel and regulatory authorities may review study data				
Assurance of confidentiality unless required by law				
Specimen/data handling including storage and destruction/disposal of specimen/data at the end of the study				
Statement of possible future use, affirming participant's right to refuse future storage and use of collected specimen/data				
Plans to develop commercial products and whether the participant will receive monetary or other benefit from such development				
Statement describing feedback of study finding whether provided or not				
Information of person(s) to contact in the study team for further information				
Statement on the approval by and contact of the secretary of the JEPeM-USM				
Appropriate language versions				

RECOMMENDATION

- ☐ APPROVED
- ☐ MINOR MODIFICATIONS
- ☐ MAJOR MODIFICATIONS
- ☐ DISAPPROVED

Reasons:

REVIEWER

Signature _____

Date:

Name

SECRETARY

Signature _____

Date: Name

Site Resources Checklist
Clinical Trials outside USM by USM Personnel
SELF-ASSESSMENT TOOL

DATE _____

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:

Complete this form if you are a USM principal investigator applying for ethical clearance from the JEPeM-USM for a clinical trial or clinical research that will be conducted outside the USM premises. This form is mandatory for the aforementioned investigator-site category. All fields should be completely filled out. If necessary, supporting documentation may be required.

Kindly fill out this form accordingly

JEPeM-USM Code:	
Principal Investigator	
Contact Number	
Contact Number	
External Site	
External Site Address	
Medical Director (External Site)	
Contact Number	
Study Sponsor	
Study Protocol Title	

A. Safety Requirements for Research Participants

Does your Institution provide a **24-hr emergency room** service?

_____ YES, proceed to A-1 and do not fill out A-2

_____ NO, proceed to A-2

A-1	**Yes**	**No**	**Remarks**
1. Does your emergency room have a fully loaded e-cart?			
2. Does your emergency room have a functioning defibrillator?			
A-2			
1. If you do not have a 24-hr emergency room service, where do you intend to refer your research participants in case of adverse events especially after office hours?	<Name of emergency facility>		
2. Describe nature of your appointment in the hospital where patients will be referred for emergency care in case of an adverse event? (NOTE: Final JEPeM-USM approval also depends on the feasibility of logistics in cases	<description>		

of adverse events to ensure safety of participants)	

B. Administrative Questions

	Yes	No	Remarks
1. Do you have an office space in the clinic that is conducive to the conduct of the clinical trial?			
2. Do you have a telephone line?			
3. Do you have a fax machine on 24 hrs?			
4. Will the sponsor be willing to shoulder expenses for monitoring of the study by the JEPeM-USM (1 visit per one year duration of study by two JEPeM-USM members and 1 Staff doing the site visit)?			
5. Are you and your clinic/hospital administrator willing to have a Memorandum of Agreement (MOA) with USM regarding the review of the study protocol and monitoring of the conduct of study by the JEPeM-USM?			
6. Where do you plan to recruit your research participants?	<name of site>		
7. How many patients with the condition of interest do you see per month in your clinic or hospital?	<quantity>		

PRINCIPAL INVESTIGATOR	Name	<Title, Name, Surname>
Date: <dd/mm/yyyy>	Signature	
ADMINISTRATOR[1]	Name	<Title, Name, Surname>
Date: <dd/mm/yyyy>	Signature	

[1] Signatory official for hospital

Site Resources Checklist
Clinical Trials outside USM by Non-USM Personnel
SELF-ASSESSMENT FORM

DATE _____

INSTRUCTIONS: Complete this form if you a **non-USM** principal investigator applying for ethical clearance from the JEPeM USM for a clinical trial or clinical research that will be conducted outside the USM premises. This form is mandatory for the aforementioned investigator-site category. All fields should be completely filled. If necessary, supporting documentation may be required.

Kindly fill out this form accordingly

JEPeM-USM Code:	
Principal Investigator	
Contact Number	
Contact Number	
External Site	
External Site Address	
Medical Director (External Site)	
Contact Number	
Study Sponsor	
Study Protocol Title	

	Yes	No	Remarks
1. Does your hospital provide a 24-hr emergency room service?			
2. Does your emergency room have a fully loaded e-cart?			
3. Does your emergency room have a functioning defibrillator?			
4. Does your hospital provide ICU care?			
5. Does your ICU have a functioning cardiac monitor?			
6. Does your ICU have a fully loaded e-cart?			
7. Does your ICU have a functioning defibrillator?			
8. Does your ICU have functioning ventilators?			
9. Do you have an office space in the hospital that is conducive to the conduct of the clinical trial?			
10. Do you have a telephone line?			
11. Do you have a fax machine on 24 hrs?			

12. Will the sponsor be willing to shoulder expenses for monitoring of the study by the JEPeM-USM (1 visit per one year duration of study by two JEPeM-USM members and 1 Staff doing the site visit)?	
13. Is your hospital administrator willing to have a Memorandum of Agreement (MOA) with USM regarding the review of the study protocol and monitoring of the conduct of study by JEPeM-USM?	
14. Where do you plan to recruit your research participants?	<name of site>
15. How many patients with the condition of interest do you see per month in your clinic/hospital?	<quantity>

PRINCIPAL INVESTIGATOR	Name	
Date:	Signature	
ADMINISTRATOR[1]	Name	
Date:	Signature	

[1] Signatory official for clinic or hospital

Letterhead

Date of issuance: <dd/mm/yyyy>

NOTICE OF MEETING

TO: **<NAME OF JEPeM-USM PANEL> Members:**
Member 1
Member 2
Member 3
Member 4
Member 5
Member 6
Member 7
Member 8

DATE OF MEETING
TIME OF MEETING
VENUE OF MEETING

AGENDA:

1. **Call to order**
2. **Determination of quorum and presence of non-institutional members**
3. **Disclosure of Conflict of interest**
4. **Reading and approval of the Minutes of the last meeting**
5. **Matters arising from the Minutes of the last meeting**
6. **Protocol review**

6.1. FULL REVIEW

6.1.1. Resubmissions or Study Protocols for Modification

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.2. Study Protocols for Initial Review

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.3. Study Protocol Amendment Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.4. Continuing Review Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.5. Final Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.6. Study Protocol Non-Compliance (Deviation or Violation) Reports:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	

Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.7. Early Study Termination Application

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.8. Queries or Complaints

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.9. SAE and SUSAR Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.1.10. Site Visit Reports:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR

6.2.1. Resubmissions or Study Protocols for Modification

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.2 Study Protocols for Initial Review

JEPeM-USM Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.3. Study Protocol Amendment Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.4. Continuing Review Applications

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.5. Final Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	

Technical Review	
Funding agency/CRO	

6.2.6. Study Protocol Non-Compliance (Deviation or Violation) Reports:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.7. Early Study Termination Application

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.8. Queries or Complaints

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.9. SAE and SUSAR Reports

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

6.2.10. Site Visit Reports:

JEPeM-USM Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	

Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding agency/CRO	

7. Other Matters

8. Adjournment

<TITLE, NAME, SURNAME> and SIGNATURE
Secretary, JEPeM-USM

UNIVERSITI SAINS MALAYSIA

Assessment for Minor/Major Modifications of Research Proposal for JEPeM Approval

JEPeM USM Code: USM/JEPeM/
Principal Investigator:
Protocol Title:
RECOMMENDATION: ☐ **APPROVED without further correction** ☐ **APPROVED UPON MINOR MODIFICATIONS as recommended** ☐ **MODIFICATIONS FOR REASSESSMENT (send back to the Reviewer)** ☐ **PI TO BE CALLED BACK**
JUSTIFICATION FOR RECOMMENDATION

REVIEWER	Signature	
Date:	Name	
SECRETARY	Signature	
Date:	Name	

Confidentiality Agreement for Guests/Observers

I, _____, understand that I am allowed to attend the JEPeM-USM meeting and/or supervised access to the JEPeM-USM files as a/an_____. In the course of the meeting of the JEPeM-USM and opening of JEPeM-USM files, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as **confidential**.

Date of JEPeM-USM Meeting : _____

JEPeM-USM Meeting Number : _____

Purpose of attendance/access : _____

_____

_____

_____

SECRETARY	Name	_____
Date:	Signature	
CHAIRPERSON	Name	_____
Date:	Signature	

Date: <dd/mm/yyyy>

<NAME OF Primary Reviewer>
<Institution/Affiliation>
<Address>

Re: <Study Protocol Title>

<JEPeM USM Code>

Dear **<TITLE > <SURNAME>**:

Appointment as a Primary Reviewer

You are invited to be a reviewer for the above-mentioned application. Please find attached a copy of the <study protocol/resubmitted study protocol/ withdrawal of study protocol application/ proposed amendments/continuing review application/final report/study non-compliance report/early study termination application/> submitted by **<Name of PI>** dated <date>. For your kind information, upon review by the Chairperson/Deputy Chairperson, this application is classified as **Full Board Review / Expedited Review**.

The results of your review need to be indicated in the following attached review form:

JEPeM USM FORM 2(C) 2019 Study Protocol Assessment Form
JEPeM USM FORM 2(D) 2019 Informed Consent Assessment Form
JEPeM USM FORM 2(H) 2019 Review of Resubmitted Protocol Form
JEPeM USM FORM 3(A) 2019 Study Protocol Amendment Submission Form
JEPeM USM FORM 3(B) 2019 Continuing Review Application Form
JEPeM USM FORM 3(C) 2019 Final Report Form
JEPeM USM FORM 3(D) 2019 Study Non-Compliance Report
JEPeM USM FORM 3(E) 2019 Early Study Termination Application Form

To facilitate protocol processing, kindly send the completed and signed review forms on or before **<cut-off date>** so that this application can be included in our next meeting scheduled on <tentative date of meeting>.

Thank you.

<NAME OF SECRETARY>
JEPeM USM

<dd/mm/yyyy>

<TITLE, NAME, SURNAME OF PI>
Principal Investigator
<Institution/Affiliation>
<Address>

Re: <Study Protocol Title> <JEPeM-USM Code>

Dear **<TITLE OF PI>**:

We wish to inform you that your study protocol has been received by the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM and has been scheduled to be reviewed by our primary reviewers. Your study has been assigned study protocol code <JEPeM-USM code>, which should be used for all communication to the JEPeM-USM Secretariat related to this study.

Should you have any questions or clarifications regarding the above, please contact the undersigned through the **JEPeM-USM** Secretariat at (09) 7672362/2354 or email at jepem@usm.my

Very truly yours,

<NAME OF SECRETARY>
JEPeM-USM

Format of the Curriculum Vitae
(Please do not exceed 3 pages)

CURRICULUM VITAE

1. **Name:**
2. **I. C. No./Passport No.:**
3. **Work Address:**

   Tel. No:

   Fax No:

   Mobile Phone No:

   E-mail Address:

4. **Academic Qualifications and Brief Career History:**

Year	Degree	Discipline	University/Work Place

5. **Field(s) of Specialization:**
6. **Research Area:**
7. **Grants in the Last 5 Years:**
8. **List NOT MORE than 10 Significant/Relevant/Related Journal Publications:**

Assessment Form for the Primary Reviewer(s) [Undergraduate/1 Year Programme of Post Graduate Student]:

Name of student :
Matric Number :
Research title :

STUDY PROTOCOL ASSESSMENT:

Items	REVIEWER'S COMMENTS
Objectives	Appropriate [ ] Not appropriate [ ]
Research design	Appropriate [ ] Not appropriate [ ]
Sample size estimation	Appropriate [ ] Not appropriate [ ]
Sampling method	Appropriate [ ] Not appropriate [ ]
Inclusion and exclusion criteria	Appropriate [ ] Not appropriate [ ]
Vulnerability of the subject	Addressed [ ] Not addressed [ ]
Recruitment of subject & informed consent seeking	Appropriate [ ] Not appropriate [ ]
Assent form requirement	Required but not prepared [ ] Acceptable [ ] Not applicable [ ]
Study area	Appropriate [ ] Not appropriate [ ]
Research tool	Appropriate [ ] Not appropriate [ ]
Data collection method	Appropriate [ ] Not appropriate [ ]
Duration of human subject involvement	Explained and acceptable [ ] Not explained [ ]
Proposed data analysis	Appropriate [ ] Not appropriate [ ]
Declaration of conflict of interest	Declared [ ] Not declared [ ]

Handling privacy & confidentiality issue	Appropriate [ ] Not appropriate [ ]
Community sensitivities & benefits	Explained [ ] Not explained [ ]
Incentives/honorarium/compensation	Appropriate [ ] Not appropriate [ ]
Flow chart	Acceptable [ ] Not acceptable [ ]
Gantt chart	Acceptable [ ] Not acceptable [ ]

PATIENT/PARTICIPANT INFORMATION SHEET AND CONSENT FORM ASSESSMENT:

Items	**REVIEWER'S COMMENTS**
List of all investigators involved	Listed completely [ ] Not complete [ ]
Research title	Appropriate [ ] Not appropriate [ ]
Introduction of study scope	Appropriate [ ] Not appropriate [ ]
Approximate number of participants	Mentioned [ ] Not mentioned [ ]
Description of the study purpose	Acceptable [ ] Not acceptable [ ]
Eligibility criteria to participate	Appropriate [ ] Not appropriate [ ]
Study procedures that will be done and responsibilities of subjects	Acceptable [ ] Not acceptable [ ]
Expected duration of participation	Mentioned [ ] Not mentioned [ ]
Foreseeable or potential risks to subject including risks to immediate family members	Explained [ ] Not explained [ ]

Expected or absence of direct benefit to participants	Explained [ ] Not explained [ ]
Community sensitivities and expected benefits to the community or to society, or contributions to scientific knowledge	Mentioned [ ] Not mentioned [ ]
Statement that the JEPeM-USM Review Panel and regulatory authorities may review study data	Mentioned [ ] Not mentioned [ ]
Assurance of confidentiality unless required by law	Mentioned [ ] Not mentioned [ ]
Specimen handling including storage and destruction of specimen at the end of the study	Mentioned [ ] Not mentioned [ ]

RECOMMENDATION

- ☐ APPROVED
- ☐ MINOR MODIFICATIONS (To be reviewed at the level of the Secretary & Chairperson)
- ☐ MINOR MODIFICATIONS (To be reviewed again by the Primary Reviewer)
- ☐ MAJOR MODIFICATIONS (To be discussed in the Full Board review meeting)
- ☐ DISAPPROVED/RESUBMISSION

Reasons:

REVIEWER

Signature _____

Date:

Name

SECRETARY

Signature _____

Date:

Name

RESEARCH PROPOSAL TEMPLATE FOR MEDICAL AND HEALTH SCIENCES

Research title:

Principal investigator (MMC No. if applicable):

Co-researchers: (MMC No. if applicable):

Introduction

Introduce study scope

Problem statement & Study rationale

Why are you conducting this study?

What is the importance of your study finding(s)?

Research Question(s)

What are the questions that you derived based on your problem statement that you would like to answer with this study?

Objective

General:

Specific:

You may use these keywords:

1. *To describe*
2. *To explore*
3. *To identify*
4. *To determine the proportion*
5. *To determine the association between the*
6. *To determine the validity of*

Literature review

Critical review of previous published studies to:

1. *Identify gaps of knowledge*
2. *Justify your study rationale*
3. *Justify your methodology*

Conceptual framework

Diagrammatic illustration of the study framework based on literature review with some text to explain the diagram.

Research design

You may need to split into phases of study

You may use these type of study designs:

1) *Cross sectional study – including questionnaire based study and study that use secondary data*
2) *Cohort or prospective study*
3) *Case control study*
4) *Interventional study –non-randomised controlled trial, randomised controlled trial, interventional study without control, any matching or blinding applied*

Study area

Where will you collect your data? Introduce the place if necessary

Study population

Reference population – The overall or big population that your study findings is able to represent. Must be appropriate for the level of your study design

Eg: Type 2 diabetic patients in Kelantan

Target population- the specific target group that you will recruit from the source population (Target population may be similar to reference population in small scale study)

Eg: Type 2 diabetic patients who attended outpatient KRK, Hosp USM

Source population / sampling pool – The source where your subject will be recruited

Eg: Type 2 diabetic patients attending Hosp. USM

Sampling frame – The list / register from where you will sample your subject

Eg: KRK attendance list for Type 2 diabetic patients TCA

Subject criteria

Inclusion & exclusion criteria (for each group if more than one group)

Sample size estimation

Estimate sample size for each objective as much as possible. Add if necessary sample size estimation when considering non response or drop out percentage.

State the software/formula used and the measures used to calculate. State the 95% CI, power of study 80%

Sampling method and subject recruitment

Sampling method – how you select a subject from the sampling frame

Research tool

List all research tool(s) and its validity, reliability, or source whenever applicable

Operational definition

Definition of certain category used in your study

Data collection method

How you will collect the data, may be written in phases. What EACH subject will undergo and the quality assurance of data collected.

How you handle sample – ensuring confidentiality, labelling, sample flow chain and storage, sample destruction post study (whenever applicable). This is applicable in both the interventional and non-interventional and allows researcher to explain how they store specimens collected from subjects. Mainly this is related to privacy protection, although this also allows evaluation on the methodology itself (suitability of sample storage method, ie. storing RNA will be different from storing DNA, etc).

Study flowchart

Diagrammatic illustration of the how the study will be conducted.

Data analysis

You may use these as a general template for descriptive statistics [note that software & its version may need to be revised accordingly]

Data will be entered and analysed using SPSS version *22*. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data will be presented as frequency (percentage).

State statistical analysis to be used for each objective

Expected result(s)

Dummy tables

Gantt chart & milestone

Provide table to illustrate the time plan of study process according to month and year in line with the study duration.

Milestone of study progress may be presented as monthly or 3-monthly.

Budget proposal [If applicable]:

State your grant type application and its status as well as the budget estimates. Please attached research grant approval if applicable.

Ethical consideration(s) [if applicable]:

1. **Subject vulnerability**

Identify and state how you are going to handle the issue. A participant is considered vulnerable if his/her ability to give true and informed consent has a potential for abuse and exploitation due to conditions such as:

1) They lack of capacity to give consent such as people with mental problem
2) There is an increase in susceptibility to coercion or exploitation.
3) There is increased risk of harm

[Taylor, 2004; Lange et al, 2013]

Vulnerable groups include those who are:

1. *Economically and medically disadvantage*
2. *Unable to give or refuse consent for themselves. These may include the underage, women and elderly*
3. *not getting any benefit personally from the research*
4. *whom the research is combine with care*

[Carl H. Coleman, 2009]

Please state how you will handle the vulnerability issues:

Example:

1. The subject is a patient under your care as a doctor. However, the patient will be given full freedom to participate or not without affecting his/her medical condition management and care.

2. The subject is your subordinate in your entity of management. The data will be independent and will not be disclose to the management authority to be used for any achievement assessment and decision related to work.

2. Declaration of absence of conflict of interest

Conflict of interest (COI) is any circumstances by other secondary bodies that may create influence on researcher's professional judgements or actions on the conduct of the study procedure or the interpretation and reporting the study findings. These may include:

1. *Payment to researcher(s) in company driven study*
2. *Benefits in any form of any researchers in the team from the study findings*

Declare the relevant situation and your absence of COI.

State how you will ensure and preserved study integrity

3. Privacy and confidentiality

You may use these as a general template [note that this is only for the confidentiality of the data that you have collected. You may need to add relevant information accordingly]

All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.

State feedback to subject if applicable

Please add relevant information with regard to your study

4. Community sensitivities and benefits

If applicable in case of issues that can triggers social stigma etc

This study will benefits the community by …. (please state if you plan to give feedback to subject)

Example:

The questionnaire or interview questions may cause distress or anxiety or are socially sensitive. Explain how you will minimise the sensitivity.

5. Honorarium and incentives

Example:

1. *Token of appreciation will be given to all responders.*
2. *Cost for transportation will be covered by the research funding*

6. Other ethical review board approval [if applicable]

Please state

i. *The name of the relevant board (eg: National Medical Research Review [NMRR,MOH])*
ii. *Status of application – pending or approve. If approved, please attach the approval letter*

References

List all references for this study proposal

RESEARCH PROPOSAL TEMPLATE FOR SOCIAL SCIENCES & OTHERS

Research title:

Principal investigator:

Co-researchers:

Introduction

Introduce study scope

Problem statement & Study rationale

Why are you conducting this study?

What is the importance of your study finding(s)?

Research Question(s)

What are the questions that you derived based on your problem statement that you would like to answer with this study?

Objective

General:

Specific:

You may use these keywords:

1. *To describe*
2. *To explore*
3. *To identify*
4. *To determine the proportion*
5. *To determine the association between the*
6. *To determine the validity of*

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2) *Cohort or prospective study*
3) *Case control study*
4) *Interventional study –non-randomised controlled trial, randomised controlled trial, interventional study without control, any matching or blinding applied*

Study location

Where will you collect your data?

Introduce the place if necessary

Study population

Reference population – The overall or big population that your study findings is able to represent. Must be appropriate for the level of your study design

Eg: Padi planters in Perak

Target population- the specific target group that you will recruit from the source population (Target population may be similar to reference population in small scale study)

Eg: Padi planters who registered at the Agricultural department, Perak

Source population / sampling pool – The source where your subject will be recruited

Eg: Padi planters in who registered at the Agricultural department from selected area in Perak

Sampling frame – The list / register from where you will sample your subject

Eg: The Agricultural department registration list of padi planters

Subject criteria

Inclusion & exclusion criteria (for each group if more than one group)

Sample size estimation

Estimate sample size for each objective as much as possible. Add if necessary sample size estimation when considering non response or drop out percentage.

State the software/formula used and the measures used to calculate. State the 95% CI, power of study 80%

Sampling method and subject recruitment

Sampling method – how you select a subject from the sampling frame

Research instruments

List all research tool(s) and its validity, reliability, or source whenever applicable

Operational definition

Definition of certain category used in your study

Data collection method

How you will collect the data, may be written in phases. What EACH participants will undergo and the quality assurance of data collected.

How you handle participants /sample collected / data – ensuring confidentiality, labelling, sample flow chain and storage, sample destruction post study (whenever applicable). This is applicable in both the interventional and non-interventional and allows researcher to explain how they store specimens collected from participants. Mainly this is related to privacy protection, although this also allows evaluation on the methodology itself (suitability of sample storage method).

Study flowchart

Diagrammatic illustration of the how the study will be conducted.

Data analysis

You may use these as a general template for descriptive statistics [note that software & its version may need to be revised accordingly]

Data will be entered and analysed using SPSS version *22*. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data will be presented as frequency (percentage).

State statistical analysis to be used for each objective

Expected result(s)

Dummy tables

Gantt chart & milestone

Provide table to illustrate the time plan of study process according to month and year in line with the study duration.

Milestone of study progress may be presented as monthly or 3-monthly.

Budget proposal [If applicable]:

State your grant type application and its status as well as the budget estimates. Please attached research grant approval if applicable.

Ethical consideration(s) [if applicable]:

1. **Participant vulnerability**

   Identify and state how you are going to handle the issue. A participant is considered vulnerable if his/her ability to give true and informed consent has a potential for abuse and exploitation due to conditions such as:

   1) They lack of capacity to give consent such as people with mental problem
   2) There is an increase in susceptibility to coercion or exploitation.
   3) There is increased risk of harm

   [Taylor, 2004; Lange et al, 2013]

   Vulnerable groups include those who are:

   1. *Economically and medically disadvantage*
   2. *Unable to give or refuse consent for themselves. These may include the underage, women and elderly*
   3. *not getting any benefit personally from the research*
   4. *whom the research is combine with care*

   [Carl H. Coleman, 2009]

   Please state how you will handle the vulnerability issues:

   Example:

   The participant is the researcher's subordinate in the organization. State how will you ensure their voluntariness to participate.

   <u>The data will be independent and will not be disclose to the management authority to be used for any performance assessment and decision related to work.</u>

2. Declaration of absence of conflict of interest

Conflict of interest (COI) is any circumstances by other secondary bodies that may create influence on researcher's professional judgements or actions on the conduct of the study procedure or the interpretation and reporting the study findings. These may include:

1. *Payment to researcher(s) in company driven study*
2. *Benefits in any form of any researchers in the team from the study findings*

Declare the relevant situation and your absence of COI.

State how you will ensure and preserved study integrity

3. Privacy and confidentiality

You may use these as a general template:[note that this is only for the confidentiality of the data that you have collected. You may need to add relevant information accordingly]

All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the participants individually.

State feedback to participants if applicable

Please add relevant information with regard to your study

4. Community sensitivities and benefits

If applicable in case of issues that can trigger social stigma etc

You may use these as a general template [note that you may need to add relevant information accordingly]:

This study will benefit the society [or the public] by the sharing of knowledge through publications in journals, books, newspaper etc.

Example:

The questionnaire or interview questions may cause distress or anxiety or are socially sensitive. Explain how you will minimise the sensitivity.

5. Honorarium and incentives

Example:

1. *Token of appreciation will be given to all participants.*
2. *Cost for transportation will be covered by the research funding*

6. Other ethical review board approval [if applicable]

Please state

i. *The name of the relevant board*
ii. *Status of application – pending or approve. If approved, please attach the approval letter*

References

List all references for this study proposal

JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA) – JEPeM USM
UNIVERSITI SAINS MALAYSIA

TEMPLATE BORANG MAKLUMAT DAN KEIZINAN PESERTA
TEMPLATE OF PARTICIPANT INFORMATION SHEET AND CONSENT FORM

(PROJEK PENYELIDIKAN)
(RESEARCH PROJECT)

Borang Maklumat dan Keizinan Peserta yang digunakan dalam Projek Penyelidikan mestilah mengikuti format maklumat berikut. Namun begitu pernyataan dan ayat yang digunakan hanyalah sebagai panduan sahaja.
The Participant Infomation and Consent Form *used in the Research Project must be according to these information formats. However, statements and phrases used only as a guide.*

- Tajuk Kajian / *Topic of the Research*
- Pengenalan / *Introduction*
- Tujuan Kajian / *Purpose of the Study*
- Kelayakan Penyertaan / *Participants Criteria*
- Prosedur-prosedur Kajian / *Study Procedures*
- Risiko / *Risks*
- Melaporkan Pengalaman Kesihatan / *Reporting Health Experiences*
- Penyertaan dalam Kajian / *Participation in the Study*
- Manfaat yang Mungkin Diperolehi / *Possible Benefits*
- Soalan / *Questions*
- Kerahsiaan / *Confidentiality*
- Tandatangan / *Signatures*

Sebagai **CONTOH**, sila rujuk Borang Maklumat dan Keizinan Peserta yang dilampirkan.
*As an **EXAMPLE**, please refer to the attached Participant Infomation Sheet and Consent Form.*

(Versi Bahasa Malaysia) / ***(Bahasa Malaysia Version)***

1. **LAMPIRAN A**
   <Sila masukkan TAJUK KAJIAN>
2. **LAMPIRAN S (Borang Keizinan Peserta)**
3. **LAMPIRAN G (Borang Keizinan Peserta – *Sampel Genetik*)**
4. **LAMPIRAN P (Borang Keizinan Penerbitan Bahan yang Berkaitan dengan Peserta)**

(Versi Bahasa Inggeris) / ***(English Version)***

1. **ATTACHMENT B**
   <Please add in the RESEARCH TITLE>
2. **ATTACHMENT S (Participant Information and Consent Form)**
3. **ATTACHMENT G (Participant Information and Consent Form – *Genetic Sample*)**
4. **ATTACHMENT P (Participant's Material Publication Consent Form)**

Information for researchers: This template serves only as an example for you to build your own Informed Consent form that suits the need and specificity of your research. **Yellow parts** in this template should be replaced with specific information related to your studies, or serve as an explanation to you. Before submitting to the JEPeM-USM Secretariat, please make sure all the **yellow parts** are replaced with specific information of your research.

MAKLUMAT KAJIAN

Tajuk Kajian **:** _____

Nama Penyelidik dan penyelidik bersama [sila sertakan no. Pendaftaran badan profesional (contoh MMC) sekiranya berkaitan **:**_____

PENGENALAN

Anda [Anak/waris anda] adalah dipelawa untuk menyertai satu kajian penyelidikan [kajian intervensi] secara sukarela. Kajian ini adalah berkaitan.....[tuliskan pengenalan skop kajian anda dalam bahasa yang mudah difahami oleh kumpulan sasaran anda]

Adalah penting bagi anda membaca dan memahami maklumat kajian sebelum anda bersetuju untuk menyertai kajian penyelidikan ini. Sekiranya anda menyertai kajian ini, anda akan menerima satu salinan borang ini untuk simpanan anda.

Penyertaan anda di dalam kajian ini dijangka mengambil masa .....[nyatakan jangkamasa bagi setiap peserta kajian perlu ikuti sehingga tamat pengumpulan data. Cth: bagi kajian melibatkan soalan kajiselidik sahaja ia adalah masa yang diambil bagi menjawab soalan tersebut. Seramai xxx orang dijangka akan menyertai kajian ini.

TUJUAN KAJIAN

Kajian ini bertujuan untuk .....[nyatakan tujuan atau semua objektif penyelidikan anda dengan bahasa yang mudah di fahami]

KELAYAKAN PENYERTAAN

Salah seorang kakitangan kajian akan membincangkan kelayakan untuk menyertai kajian ini. Adalah penting anda berterus terang kakitangan tersebut [Jika berkaitan boleh ditambah “termasuk sejarah kesihatan anda].

Kajian ini akan melibatkan individu yang .....[nyatakan kriteria pemilihan “inclusion criteria” kajian]

Kajian ini tidak akan melibatkan individu yang .....[nyatakan kriteria penolakan “exclusion criteria” kajian]

Jika peserta kajian adalah dipilih sebagai normal control, perlu dinyatakan definisi “inclusion criteria” dan “Exclusion criteria” sepertimana di atas.

PROSEDUR-PROSEDUR KAJIAN

Sila nyatakan setiap langkah atau prosedur yang perlu dilalui oleh setiap subjek sehingga akhir proses pengumpulan data
Bagi kajian yang menggunakan soalan kaji selidik, sila nyatakan dengan ringkas skop soalan yang akan di berikan, jumlah soalan dan anggaran jangkawaktu yang akan diambil
Bagi kajian yang melibatkan intervensi, mestilah di nyatakan dengan terperinci setiap intervensidan lawatan susulan yang akan dilakukan. Perlu juga dinyatakan pemilihan rawak kumpulan kawalan atau kajian intervensi jika berkaitan

RISIKO

Nyatakan risiko (fizikal/emosi) yang mungkin di hadapi oleh subjek kajian sepanjang tempoh mengikuti kajian ini. Risiko mungkin juga melibatkan pasangan subjek (contohnya soalan berkaitan peranan ibubapa dalam mendidik anak anak di mana pasangan subjek juga memainkan peranan).

Sila maklumkan kepada kakitangan kajian sekiranya anda menghadapi sebarang masalah atau mempunyai sebarang maklumat penting yang mungkin mengubah persetujuan anda untuk terus menyertai kajian ini.

MELAPORKAN PENGALAMAN KESIHATAN (Jika Kajian Melibatkan Kesihatan SAHAJA)

Sila hubungi kakitangan berikut pada bila-bila masa sekiranya anda mengalami sebarang masalah kesihatan, samada berkaitan atau tidak berkaitan dengan kajian ini.
Dr. <Nama Penyelidik> **[No. Pendaftaran Penuh Majlis Perubatan Malaysia:_____]** di talian <No. Telefon> atau <No. H/P> secepat mungkin.

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak untuk menyertai kajian ini atau menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh kakitangan kajian ini tanpa persetujuan anda sekiranya anda didapati tidak sesuai untuk meneruskan kajian ini berdasarkan protokol kajian. Kakitangan kajian akan memaklumkan anda sekiranya anda perlu diberhentikan dari menyertai kajian ini.

MANFAAT YANG MUNGKIN [Manfaat terhadap Individu, Masyarakat, Universiti]

Prosedur kajian ini akan diberikan kepada anda tanpa kos. Anda boleh menerima maklumat tentang .....[nyatakan manfaat yang boleh diperolehi oleh peserta dengan mengikuti kajian ini seperti pemeriksaan kesihatan atau maklumat berkenaan skop kajian]

Hasil kajian ini diharapkan, dapat memberi manfaat kepada masyarakat umum untuk.....[nyatakan manfaat komuniti]

Anda tidak akan menerima sebarang pampasan kerana menyertai kajian ini. Namun sebarang keperluan perjalanan berkaitan dengan penyertaan ini akan diberikan.[SEKIRANYA BERKAITAN]

PERSOALAN

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

<Nama Penyelidik> & <No. MMC>[jika berkaitan]
<Jabatan>
<Pusat Pengajian>
<USM Kampus Kesihatan>
<No. untuk dihubungi>

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Bahagian Penyelidikan dan Inovasi (P&I)
USM Kampus Kesihatan.
No. Tel: 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

ATAU

Cik Nor Amira Khurshid Ahmed
Sekretariat Jawatankuasa Etika Penyelidikan (Manusia) USM
Pejabat Pengurusan dan Kreativiti Penyelidikan (RCMO)
USM Kampus Induk, Pulau Pinang.
No. Tel: 04-6536537
Email: noramira@usm.my

KERAHSIAAN

Maklumat yang anda berikan akan dirahsiakan oleh kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian ini tidak akan mengenalpasti anda secara perseorangan. Hasil kajian mungkin akan diterbitkan untuk tujuan perkongsian ilmu.

Semua borang kajian dan data yang anda berikan termasuk rekod perubatan anda [JIKA BERKAITAN] yang asal mungkin akan disemak oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori bagi tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat anda akan disimpan dalam komputer dan hanya kakitangan kajian yang dibolehkan sahaja dibenarkan untuk mendapatkan dan memproses data tersebut.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemprosesan data seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan (Lihat contoh Borang Keizinan Peserta di **LAMPIRAN S** atau **LAMPIRAN G (untuk sampel genetik)** atau **LAMPIRAN P**).

LAMPIRAN S

Borang Keizinan Peserta
(Halaman Tandatangan)

Tajuk Kajian: _____

Nama Penyelidik: _____

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

_____

Nama Peserta

_____

No. Kad Pengenalan Peserta

_____ _____

Tandatangan Peserta atau Wakil Sah

Tarikh (dd/MM/yy)
(Masa jika perlu)

_____ _____

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan

Tarikh (dd/MM/yy)

_____ _____

Nama Saksi dan Tandatangan

Tarikh (dd/MM/yy)

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

Borang Keizinan Peserta untuk Pengambilan *Sampel Genetik* (Halaman Tandatangan)

Tajuk Kajian: _____

Nama Penyelidik: _____

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

_____

Nama Peserta

_____

No. Kad Pengenalan Peserta

_____ _____

Tandatangan Peserta atau Wakil Sah

Tarikh (dd/MM/yy)
Masa (jika perlu)

_____ _____

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan

Tarikh (dd/MM/yy)

_____ _____

Nama Saksi dan Tandatangan

Tarikh (dd/MM/yy)

Nota:
i) Lebihan sampel kajian ini akan dilupuskan dan tidak akan digunakan untuk tujuan lain kecuali setelah mendapat kebenaran daripada Jawatankuasa Etika Penyelidikan (Manusia), USM.
ii) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

LAMPIRAN P

Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Peserta Kajian (Halaman Tandatangan)

Tajuk Kajian: _____

Nama Penyelidik: _____

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks – contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

_____ _____

Nama Peserta

_____ _____ _____

No. Kad Pengenalan Peserta T/tangan Peserta **Tarikh** (dd/MM/yy)

_____ _____

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan **Tarikh** (dd/MM/yy)

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

CONTOH **ATTACHMENT B**

RESEARCH INFORMATION

Research Title: _____

Name of main and co-Researcher [please state professional bodies registration no. Eg: MMC no. If relevant]:

INTRODUCTION

You [person under your care / guardian] are invited to take part voluntarily in a research [interventional research]. This research is about ... [introduce your research scope in a simple languange by avoiding techincal jargons appropriate for your research target subjects]

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to ...[state the estiamated time per subject to finish all data collection time] . This study is estimated to include up to xxx participants.

PURPOSE OF THE STUDY

The purpose of this study are to determine ....[state your research objectives in a simple language]

PARTICIPANTS CRITERIA

The research team members will discussed your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history [if relevant ONLY].

This study will include individual who are.....[state your inclusion criteria, simplfy whenever possible]
This study will not incude individual who are ....[state your exclusion criteria, simplfy whenever possible]

If the participant is selected as a “normal control” then it should state clearly on the inclusion and exclusion criteria using the similar template as above

STUDY PROCEDURES

State in detail ALL steps that had to be taken or done to EACH subjects until the end of the data collection process.

For a questionnaire based research, state briefly the scope of the question to be provided, total number of questions ask and estimated time required to fill in the questionnaire
For an interventional study, please state in detail on the intervention that the subject will received including all the required visit expected. It is also important to note that the allocation of subject to either control or intervention group are done randomly or randomization method used.

RISKS

State the possible risk that may arise from their participation in your study. Risk may include the direct risk to the participants or their partner / spouse

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

Dr. <researcher name> **[MMC Registration No._____]** at <phone No.> or <H/P No.>.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discussed with you if the matter arises.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

State the possible benefit that the participants will received from participating in this study.

This study finding may benefit the community by....
You will not recieve any compensation from this study. However you may get reimbursement for your travelling cost while in the study duration [if relevant]

QUESTIONS

If you have any question about this study or your rights, please contact;

<Name of Researcher> & <No. MMC>
<Department of>
<School>
<USM Health Campus>
<Contact No. Office > <Contact No. HP>

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang
Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page **[ATTACHMENT S or ATTACHMENT G (for genetic sample only) or ATTACHMENT P]**

Subject Information and Consent Form (Signature Page)

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant I.C No

_____ _____

Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____

Name of Individual
Conducting Consent Discussion

_____ _____

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

Subject Information and Consent Form
(Signature Page – Genetic Sample)

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant I.C No.

_____ _____

Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____

Name of Individual
conducting Consent Discussion

_____ _____

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.
ii) Excess samples from this research will not be used for other reasons and will be destroyed with the consent from the Human Research Ethics Committee, USM.

Participant's Material Publication Consent Form
Signature Page

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

Participant Name

_____ _____ _____

Participant I.C No. **Participant's Signature** **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Note: i) All participants who are involved in this study will not be covered by insurance.

INFORMED CONSENT FORM (TEMPLATE) – GENOMIC - ENGLISH

RESEARCH SUBJECT INFORMATION AND CONSENT FORM FOR WHOLE- GENOME/GENETIC RELATED STUDIES

(WHOLE GENOME/GENETIC RESEARCH PROJECT)

A. ***Research Subject Infomation and Consent Form*** *used in the Genetic/Whole-Genome related Research Project must be according to these information formats:*

- *Topic of the Research*
- *Introduction*
- *Purpose of the Study*
- *Study Procedures*
- *Risks*
- *Possible Benefits*
- Incidental Findings
- Disclosure of Research Results
- *Questions*
- *Confidentiality*
- Withdrawal from the study
- *Signatures*

B. *As an* ***EXAMPLE****, please refer to the attached Research Subject Infomation and Consent Form.*

1. **ATTACHMENT D – Research Information**
2. **ATTACHMENT E – Research Subject Information and Consent Form**
3. **ATTACHMENT F – Subject's Material Publication Consent Form**

C. **Information for researchers:** This template serves only as an example for you to build your own Informed Consent form that suits the need and specificity of your research. However, all components of Informed Consent as specified in (A) above must be present. Red parts in this template should be replaced with specific information related to your studies, or serve as an explanation to you. Before submitting to the JEPeM-USM Secretariat, please make sure all the red parts are no longer there and replaced with specific information of your research.

EXAMPLE **ATTACHMENT D**

RESEARCH INFORMATION

Research Title : _____

Researcher's Name : _____
(If applicable, MMC/GCP)

INTRODUCTION

You are invited to take part voluntarily in a research study of *[specify the study]*. Before agreeing to participate in this research study, it is important that you read and understand this form. If you participate, you will receive a copy of this form to keep for your records.

- DNA, or **deoxyribonucleic acid**, is the hereditary material in humans and almost all other organisms. Nearly every cell in a person's body has the same DNA. Most DNA is located in the core of the cell, termed nucleus (where it is called nuclear DNA), but a small amount of DNA can also be found in other parts of the cell which mostly produce energy, termed mitochondria.

- The information in DNA is stored as a code made up of four chemical bases: adenine (A), guanine (G), cytosine (C), and thymine (T). Human DNA consists of about 3 billion bases, and more than 99 percent of those bases are the same in all people.

- The order, or sequence, of these bases determines the information available for building and maintaining an organism, similar to the way in which letters of the alphabet appear in a certain order to form words and sentences.

- DNA can replicate, or make copies of itself. Each strand of DNA can serve as a pattern for duplicating the sequence of bases. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell.

- DNA of a person is a combination of roughly half the DNA of the father and half DNA of the mother. People from the same family or ethnicity may share similar DNA variations.

- Science behind DNA has been in continuous exploration in order to understand biology of life, either normal or abnormal.

PURPOSE OF THE STUDY *[whole genome, exome sequencing or other whole genomics-related analysis research]*

We are requesting your permission to perform whole *[specify type of analysis, i.e. genome and/or exome sequencing]* on your *[specify type of specimen, i.e. blood and/or tissue samples]* and link this to your medical and/or family history.

Whole *[specify type of analysis, i.e. genome and/or exome]* sequencing will determine the exact order of the base pairs (chemical letters) in *[specify the tissue sampled]*. Your sample(s), *[specify any correlations, i.e. medical and family history information]* will help us study how genes *[specify purpose of analysis]*.

STUDY PROCEDURES

As much as *[specify how much of sample will be taken]* of your *[specify the type of tissue/specimen ie. blood]* will be withdrawn by a qualified officer. The *[specimen]* will then be processed to obtain *[specify the type of molecular substance extracted ie. DNA, mRNA, total RNA, etc.]*. This will be processed using *[specify methodology]* to identify *[specify what will be identified, eg. mutation of a gene – be as specific or as broad as researchers intend to explain, what is the nature of likely future use of the sample]*.

- Explain if Research Subject is required to visit the HUSM, how many times and for what purpose in each visit
- Explain if other medical examination will be carried out
- Explain if analysis on medical record will be carried out

RISKS

Physical Risks [as appropriate]

Obtaining blood can ocassionally cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs.

Psychological or Social Risks Associated with Possible Loss of Privacy

Your privacy is very important to us and we will use many safety measures to protect your privacy. *[specify the safety measures taken]*. Neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number.

However, in spite of all of the safety measures, it is not possible to absolutely seal your identity from being revealed. Below are some situations that illustrate some risks:

1. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

_____
Signature of Research Subject or Legal Representative

2. People may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

_____
Signature of Research Subject or Legal Representative

3. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

_____
Signature of Research Subject or Legal Representative

4. Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others.

_____
Signature of Research Subject or Legal Representative

5. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives.

_____
Signature of Research Subject or Legal Representative

6. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease.

_____
Signature of Research Subject or Legal Representative

Risk associated with the DNA Act 2009

Malaysian DNA Act 2009 stated that in the case of crime investigation, the police reserve the authority to collect DNA information of crime suspects. In such case where you are suspected of a crime, become subject of police crime investigation and the police request to collect your DNA information, the researchers are obliged to do so.

_____
Signature of Research Subject or Legal Representative

There also may be other privacy risks that we have not foreseen.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]
(Researchers are required to choose one or specify in case both are applicable)

Are there any benefits to participating in the project? No Benefit

You will not benefit personally from giving a sample for this project because this kind of research usually takes a long time to produce medically useful results. However, your participation will increase our understanding about *[specify the knowledge or other scientific benefit gained from this study]*. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.

Are there any benefits to participating in the project? Benefit

Possible benefits to you could include: [include as applicable]

- A specific change in your genes is the reason for your personal history of [specify the disease under study].
- Information about the risks for [specify the disease under study] to your children which may help manage their healthcare.
- New and better treatments may be an option depending on the genetic result(s).

This study may increase our understanding about *[specify the knowledge or other scientific benefit gained from this study]*. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.

INCIDENTAL FINDINGS

Gene changes may be identified that are not related to this research study. These are known as “incidental medical findings”.
These include

- Changes in genes that are related to diseases other than that studied in the current research
- Changes in genes that are not known to cause any disease. These are known as normal variations
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations

Where knowledge is available presently
It is possible that we will find gene changes or genetic variants that are unrelated to this study. If we find a change in a gene that is important to you or your family’s health, please let us know your preference by initialing one of the following statements:

_[ ]___ I DO NOT want to be contacted if genetic variants with potential health implications (PHIs)* are discovered.

_[ ]___ I DO want to be contacted if genetic variants with PHIs* are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

_____
Signature of Research Subject or Legal Representative

If you choose the first option, we will not inform you of the incidental finding and will not commence on further clinical confirmation of the results.

If you choose the second option, the results will need to be confirmed in a clinical laboratory. *[specify how long you will look for other relevant genetic changes, i.e. one time only, for a period of time]* If you want this to be done, we will draw an additional blood sample and send it for confirmatory testing. Once the results are available, if you would like to receive your results we will offer to have you come to Hospital Universiti Sains Malaysia (at our expense) to have genetic education and counseling to explain this result.

If you do not want to come to Hospital Universiti Sains Malaysia, we will help you find a local genetic healthcare provider who can explain it to you (at your expense).

Where knowledge is not available presently but may become available in the future
If we find gene changes that are not known to be important at this time, we will not share that information with you. However, as this is a rapidly changing field, it is possible that genetic variants that are not known to be important at this time may be shown to be important at a later date. If you are receiving care from another physician who thinks that this testing may be of use in your care and treatment, you may contact us at any time and we will share the results with your physician.

Please let us know your preference by initialing one of the following statements:

_[ ]___ I DO NOT want to be recontacted if genetic variants with PHIs* are discovered.

_[ ]___ I DO want to be recontacted if genetic variants with PHIs* are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

_____
Signature of Research Subject or Legal Representative

Significant non health-related Incidental findings
(This part is optional, only when applicable)
If we find incidental findings which are not related to your health but may be of significant importance to you or your family (eg. incidental finding of non-paternity), please let us know your preference by initialing one of the following statements:

_[ ]___ I DO NOT want to be contacted if genetic variants of such nature are discovered.

_[ ]___ I DO want to be contacted if genetic variants of such nature are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)

_____
Signature of Research Subject or Legal Representative

*Potential Health Implications (PHIs): This study involves investigating your whole genome. There are around 3 billion pairs of DNA in each human cells parted functionally into around 30,000 genes. Each of which variations may implicate certain risks to some diseases. Most of the variations confer low risks to some diseases, but some may confer significant risks. While it is not possible to inform precisely all the risks by the time of this consent process such information will become available, if you indicated so above, as data of your whole genome become available.

[Note for researchers: This explanation above best suits whole-genome sequencing. Researchers may adjust this explanation to suit into their specific nature of research, ie. microarray-based experiments that investigate only a few thousand or millions of SNPs and CNVs)

DISCLOSURE OF RESEARCH RESULTS
(Researchers are required to choose one or specify in case both are applicable)

Research Results-non disclosure
We will not give you any individual results from your whole [genome and/or exome] sequencing. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a condition, such as communicable disease that we are required by law to report. *[Specify whether and how you will summarize research results for participants.]*

Research Results-disclosure
When we have useful results from the genome sequencing we have done, we will contact you and ask you if you want to learn the results. We will ask you to come back to the Hospital Universiti Sains Malaysia to learn the results in *[specify the time required from specimen collection to return of result to the participant, if possible]*. You will meet with professionals with the expertise to help you learn more about the risks, benefits and limitations of learning your research results. If you then decide to receive your results, the research team will explain the meaning of these results and any implications for your and/or your family's health.

CONTACT PERSON/QUESTIONS

Please contact the Principal Investigator, *[name of Principal Investigator]* at phone number *[give cellphone number]* and/or email *[give email address]* for all research-related matters and in the event of research-related injuries. If you feel uncomfortable contacting the Principal Investigator, you could also contact the *[give name of collaborator/other team researcher]* (collaborator/research team contact) at phone number *[give cellphone number]* and/or email *[give email address]*.

For an independent opinion regarding the research and the rights of research participants, you may contact a staff at the USM Research Ethics Committee

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang
Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.

Your samples will be anonymous/non-identifiable (i.e. personal identifiers will not be kept with your sample and the sample will not have a code number that can be used to identify you) or coded and considered de-identified (i.e. any identifying information such as name will be replaced with a code and only a few authorized people will have access to this code to link samples and data back to personal identifiers).

(Optional, in case of reportable conditions, such as HIV status)
As per government regulation [specify the regulation, if any], we are required to report your condition [specify the condition] to the Ministry of Health [specify the MOH office concerned].

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

PUBLIC DATA RELEASE
(This part is optional depending on whether researcher intend to submit the data to a shared database)

Data obtained from this study, which does not directly identify you personally, may be submitted to a [nationally/internationally] shared database [specify the name of the database and if it is a paid or free access] and published in scientific journal. Data that has been submitted to a database or published in scientific journal can not be retracted if you withdraw from the study and request that all your data be eliminated and remaining biological samples be destroyed. In this regard, it is has to be understood that submission into database and publication in scientific journals limit the efforts of withdrawal.

Please let us know your preference by initialing one of the following statements:

_[ ]___ I DO NOT want the data generated from my biological specimens to be submitted into the database

_[ ]___ I DO want the data generated from my biological specimens to be submitted into the database

_____
Signature of Research Subject or Legal Representative

SAMPLE/DATA STORAGE AND WITHDRAWAL FROM STUDY

Any blood or tissue specimens obtained during the course of this study will be stored and analyzed only for the purposes of this study for a period not exceeding *[specify time length]* years, and will be destroyed after completion of the study. However, if you agree to allow us to keep the tissues or blood samples for future studies after this project is completed, you will be requested to sign at the appropriate part of the consent form below.

Your biological sample will be destroyed and your data will be eliminated when you express withdrawal from the study

_____
Signature of Research Subject or Legal Representative

If you would like to withdraw from this project you can contact *[Insert Name & Contact Information of Principal Investigator]* at *[Insert Name of Institution]* and he/she will destroy any remaining samples and written information of yours that have been obtained for the study. However, the samples and data generated from your samples that have already been distributed to other research centers or placed in the research databases or published in scientific journals or other form of publications cannot be withdrawn.

SIGNATURES

To be entered into the study, you or a legal representative must sign and date the signature page **[ATTACHMENT E and ATTACHMENT F]**

Research Subject Information and Consent Form (Signature Page)

Research Title: _____

Researcher's Name: _____

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose, procedures and possible risks of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

Name of Subject (>12 years),	Signature	Date
_____	_____	_____

Name of Parent or Legally Accepted Representative	Signature	Date
_____	_____	_____

Translator Information
The study has been explained to the participant / legally acceptable representative in [specify the language used) language by [name of translator].

Witness Statement
I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Witness	Signature	Date
_____	_____	

Investigator Statement
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the study.

Name of Investigator / Person administering consent	Signature	Date	Time Start	Time End
_____	_____	_____	_____	_____

ATTACHMENT F

Research Subject's Material Publication Consent Form
Signature Page

Research Title: _____

Researcher's Name: _____

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____ _____

Research Subject Name (Print or type) **Research Subject Initials** or **Number**

_____ _____ _____

Research Subject I.C No. Research Subject's Signature **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

BORANG MAKLUMAT DAN KEIZINAN PESAKIT/SUBJEK KAJIAN
KAJIAN KESELURUHAN GENOM/GENETIK

(PROJEK PENYELIDIKAN KESELURUHAN GENOM/GENETIK)

A. **Borang Maklumat dan Keizinan Pesakit/Subjek** yang digunakan dalam Projek Penyelidikan Keseluruhan Genom/Genetik mestilah mengikuti format maklumat berikut:

- Tajuk Kajian
- Pengenalan
- Tujuan Kajian
- Prosedur-prosedur Kajian
- Risiko
- Manafaat yang Mungkin Diperolehi
- Penemuan Sampingan
- Pendedahan Keputusan Kajian
- Soalan
- Kerahsiaan
- Penarikan daripada kajian
- Tandatangan

B. Sebagai **CONTOH**, sila rujuk Borang Maklumat dan Keizinan Pesakit yang dilampirkan.

1. **LAMPIRAN A – Maklumat Kajian**
2. **LAMPIRAN B – Borang Keizinan Pesakit**
3. **LAMPIRAN C – Borang Keizinan Penerbitan Bahan yang Berkaitan dengan Subjek**

C. **Maklumat untuk penyelidik:** Templat borang ini hanyalah merupakan contoh untuk anda bagi menyediakan satu Borang Maklumat dan Keizinan yang bersesuaian dengan keperluan dan pengkhususan penyelidikan anda. Walaubagaimanpun, semua komponen dan bahagian dalam Borang Maklumat dan Keizinan ini perlulah dikekalkan sebagaimana yang telah disertakan pada bahagian (A). Bahagian yang telah diwarnakan merah perlulah digantikan dengan maklumat dan penjelasan berkaitan dengan penyelidikan anda. Sebelum menghantar Borang Maklumat dan Keizinan ini kepada pihak Setiausaha JEPeM-USM, sila pastikan bahawa semua bahagian diwarnakan merah telah digantikan dengan maklumat terperinci berkenaan penyelidikan ini.

CONTOH **LAMPIRAN A**

MAKLUMAT KAJIAN

Tajuk Kajian : _____

Nama Penyelidik : _____

(Jika berkenaan, sila sertakan MMC/GCP)

PENGENALAN

Anda dipelawa untuk mengambil bahagian secara sukarela dalam kajian [nyatakan kajian]. Sebelum anda bersetuju menyertai kajian penyelidikan ini, penting bagi anda untuk membaca dan memahami borang ini. Jika anda menyertai kajian ini, anda akan menerima satu salinan borang untuk disimpan sebagai rekod anda.

- DNA atau asid deoksiribonuklik merupakan molekul keturunan bagi manusia dan organisma lain. Hampir setiap sel dalam badan manusia mempunyai DNA yang sama. Kebanyakan DNA terdapat didalam inti sel yang dikenali sebagai nukleus (dipanggil juga nuklear DNA). Namun begitu sebilangan kecil DNA boleh juga ditemui dalam bahagian lain sel yang kebanyakannya mengeluarkan tenaga dan dikenali sebagai mitokondria.
- Maklumat DNA yang disimpan sebagai kod terdiri daripada empat bes kimia: adenin (A), guanin(G), sitosin(C) dan taimin(T). DNA manusia mengandungi 3 bilion bes dan lebih 99 peratus daripada bes tersebut sama dalam semua manusia.
- Aturan atau jujukan bes ini menentukan maklumat yang ada untuk membina dan menentukan sesuatu organisma, sama seperti abjad yang berada dalam susunan tertentu untuk dijadikan perkataan dan ayat.
- DNA boleh direplika atau membuat salinannya sendiri. Setiap bebenang DNA boleh dijadikan sebagai pola pendua jujukan bes. Ianya kritikal semasa pembahagian sel kerana setiap sel baru memerlukan salinan tepat DNA daripada sel asal.
- DNA seseorang individu merupakan kombinasi separuh DNA ayah and separuh DNA ibu. Individu daripada keluarga atau etnik yang sama berkongsi variasi DNA yang sama.
- Eksplorasi bidang sains mengenai DNA masih berterusan untuk memahami biologi kehidupan samada ia normal atau abnormal.

TUJUAN KAJIAN *[keseluruhan genom, turutan exome atau kajian analisis berkait genomik keseluruhan lain]*

Kami ingin memohon persetujuan anda untuk melakukan [nyatakan jenis analisis, seperti genome dan/atau jujukan exome] keatas [nyatakan jenis spesimen, seperti darah dan/atau sampel tisu] anda dan mengaitkannya kepada sejarah perubatan anda dan/atau keluarga.

[nyatakan jenis analisis, seperti genom dan/atau exome] jujukan keseluruhan akan menentukan aturan tepat pasangan tapak (persamaan kimia) dalam [nyatakan sampel tisu]. Sampel anda, [nyatakan kolerasi , seperti sejarah maklumat perubatan dan keluarga] akan membantu kami mengkaji bagaimana gen [nyatakan tujuan analisis].

PROSEDUR-PROSEDUR KAJIAN

Sebanyak [nyatakan jumlah sampel akan diambil] [nyatakan jenis tisu/spesimen seperti darah] anda akan diambil oleh pegawai yang berkelayakan. [Spesimen] akan diproses untuk mendapatkan [nyatakan jenis bahan molekular yang diekstrak seperti DNA,mRNA, Total TNA,dan lain-lain]. Ia akan diproses menggunakan [nyatakan metodologi] untuk mengenalpasti [nyatakan apa yang akan di kenalpasti seperti, mutasi gen- secara spesifik atau umum seperti yang pengkaji ingin jelaskan, apakah kegunaan sampel tersebut pada masa hadapan].

- Jelaskan jika subjek kajian perlu ke HUSM, kekerapan dan tujuan setiap lawatan.
- Jelaskan jika pemeriksaan perubatan lain akan dibuat
- Jelaskan jika analisis rekod perubatan akan dibuat

RISIKO

Risiko Fizikal [Jika berkenaan]

Pengambilan sampel darah boleh menyebabkan sakit, pendarahan, lebam atau bengkak pada tempat jarum dicucuk. Kadangkala ada yang pengsan tetapi jarang berlaku jangkitan.

Risiko Psikologikal dan Sosial Berkaitan dengan Kehilangan Kerahsiaan

Kerahsiaan diri anda penting kepada kami dan kami akan mengambil langkah-langkah keselamatan untuk melindungi kerahsiaan anda. [nyatakan langkah keselamatan yang diambil]. Maklumat yang biasanya digunakan untuk mengenalpasti anda seperti nama, alamat, nombor talipon atau kad pengenalan anda tidak disimpan dalam databes awam atau databes capaian terkawal yang dibangunkan untuk projek ini.

Namun begitu, mustahil untuk melindungi identiti anda daripada terdedah sepenuhnya walaupun semua langkah keselamatan telah diambil. Situasi-situasi dibawah ini menggambarkan risiko yang mungkin:

1. Walaupun maklumat genetik itu unik kepada anda, maklumat genetik tersebut dikongsi bersama dengan anak-anak anda, ibubapa, abang, kakak dan keluarga yang mempunyai pertalian darah. Yang demikian, maklumat genetik daripada mereka boleh digunakan untuk mengenalpasti anda. Sama juga kemungkinan maklumat genetik anda digunakan untuk mengenalpasti mereka.

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Tandatangan Subjek Kajian atau Wakil Sah

2. Pada masa hadapan kemungkinan ada yang membangunkan cara yang membolehkan seseorang mengaitkan maklumat genetik atau perubatan anda dalam databes kami kepada anda semula. Contohnya, seseorang boleh membandingkan maklumat daripada databes kami dengan maklumat anda (atau saudara mara) dalam databes lain dan dapat mengenalpasti anda (atau saudara mara anda)

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Tandatangan Subjek Kajian atau Wakil Sah

3. Kemungkinan juga akan terdapat pelanggaran kepada keselamatan sistem komputer yang digunakan untuk menyimpan kod yang mengaitkan maklumat genetik dan perubatan kepada anda.

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Tandatangan Subjek Kajian atau Wakil Sah

4. Memandangkan sesetengah variasi genetik boleh membantu meramal masalah kesihatan anda dan keluarga, maklumat ini mungkin penting untuk pengamal kesihatan, syarikat insuran nyawa dan lain-lain.

_____
Tandatangan Subjek Kajian atau Wakil Sah

5. Pola variasi genetik juga boleh digunakan oleh agensi penguatkuasa undang-undang untuk mengenalpasti seseorang atau saudara mara mereka.

_____
Tandatangan Subjek Kajian atau Wakil Sah

6. Oleh itu terdapat juga potensi maklumat genetik anda digunakan dalam pelbagai cara yang boleh menyebabkan keluarga anda tertekan, seperti pendedahan bahawa anda (atau saudara mara) membawa penyakit genetik.

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Tandatangan Subjek Kajian atau Wakil Sah

Risiko Berkait dengan Akta DNA 2009

Akta DNA 2009 Malaysia menyatakan dalam penyiasatan kes jenayah, polis mempunyai kuasa untuk mengumpul maklumat DNA suspek jenayah. Dalam kes tersebut dimana anda adalah suspek jenayah, menjadi subjek penyiasatan jenayah polis dan polis meminta maklumat DNA anda dikumpul, pihak penyelidik perlu memenuhi permintaan tersebut.

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Tandatangan Subjek Kajian atau Wakil Sah

Kemungkinan masih ada risiko kerahsiaan lain yang tidak kami jangkakan.

MANFAAT YANG MUNGKIN [Manfaat kepada Individu, Komuniti , Universiti]
(Penyelidik perlu memilih satu atau lebih dan sila perincikan mana berkenaan]

Adakah penyertaan dalam kajian ini memberi manfaat? Tiada manfaat

Anda tidak akan memperoleh manfaat secara individu dengan pemberian sampel untuk projek ini kerana selalunya kajian ini mengambil masa yang lama untuk mendapatkan keputusan perubatan yang berguna. Namun begitu, penyertaan anda akan meningkatkan pemahaman kami mengenai [nyatakan pengetahuan atau manfaat saintifik lain daripada kajian ini]. Kami percaya maklumat yang didapati daripada kajian ini mungkin menyumbang kepada penjagaan perubatan, rawatan dan pencegahan masalah untuk orang lain pada masa hadapan.

Adakah penyertaan dalam kajian ini memberi manfaat? Bermanfaat

Manfaat yang mungkin kepada anda termasuk:[nyatakan jika berkenaan]

- Perubahan spesifik kepada gen anda adalah penyebab kepada sejarah peribadi anda yang [nyatakan penyakit yang dikaji].
- Maklumat risiko untuk [nyatakan penyakit yang dikaji] anak anda yang mungkin membantu pengurusan penjagaan kesihatan mereka.
- Rawatan baru dan lebih baik mungkin boleh menjadi pilihan bergantung kepada keputusan genetik.

Kajian ini mungkin meningkatkan pemahaman kami mengenai [nyatakan pengetahuan atau manfaat saintifik lain daripada kajian ini] Kami percaya maklumat yang diperolehi daripada kajian ini mungkin menyumbang kepada penjagaan perubatan, rawatan dan pencegahan masalah untuk orang lain di masa hadapan.

PENEMUAN SAMPINGAN

Ada juga kemungkinan kajian ini dapat mengenalpasti perubahan genetik yang tidak berkait dengan kajian. Ianya dikenali sebagai 'penemuan perubatan sampingan'.

Ia termasuk, tetapi tidak terbatas pada:

- Perubahan pada gen yang berkait dengan penyakit lain yang tidak dikaji masa kajian ini.

- Perubah pada gen yang tidak diketahui akan menyebabkan penyakit. Ini dikenali sebagai variasi normal.

- Perubahan baru pada gen dan tidak pasti kepentingannya secara klinikal. Ia bermaksud bahawa kami tidak tahu jika ia boleh menjadi penyebab atau menyumbang kepada penyakit atau ia adalah variasi normal.

Pengetahuan ada pada masa kini
Kami mungkin akan menemui perubahan gen atau varian genetik yang tidak berkait dengan kajian ini. Jika kami menemui perubahan dalam gen yang penting untuk kesihatan anda dan keluarga, sila nyatakan pilihan anda dengan menulis parap nama pada kenyataan berikut:
__[ ]___SAYA TIDAK MAHU dihubungi jika varian genetik yang mempunyai Potensi Implikasi Kesihatan (PIK) ditemui.
__[ ]___SAYA MAHU dihubungi jika varian genetik yang mempunyai Potensi Implikasi Kesihatan(PIK) ditemui. (Anda akan diberi pilihan samada mahu diberi penerangan atau tidak mengenai perubahan genetik yang kami temui).

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Tandatangan Subjek Kajian atau Wakil Sah

Jika anda memilih pilihan pertama, kami tidak akan beritahu anda mengenai penemuan sampingan dan tidak akan meneruskan pengesahan klinikal keatas keputusan tersebut.

Jika anda memilih pilihan kedua, keputusan akan disahkan dalam makmal klinikal.[nyatakan tempoh masa kajian yang anda akan lakukan untuk perubahan genetik yang lain seperti sekali sahaja atau untuk tempoh masa tertentu]. Jika anda ingin ia dilakukan, kami akan mengambil sampel darah tambahan dan dihantar untuk ujian pengesahan. Apabila keputusan telah ada dan anda ingin menerima keputusan tersebut kami akan mempelawa anda datang ke Hospital Universiti Sains Malaysia (perbelanjaan sendiri) untuk mendapatkan penerangan dan kaunseling untuk menerangkan tentang keputusan ini.

Jika anda tidak mahu datang ke Hospital Universiti Sains Malaysia, kami akan bantu anda untuk mencari pengamal kesihatan genetik setempat yang boleh menerangkan tentangnya kepada anda (perbelanjaan sendiri).

Pengetahuan tidak ada pada masa ini tapi mungkin akan ada pada masa hadapan
Jika kami menemui perubahan gen yang tidak diketahui kepentingannya pada masa ini, kami tidak akan berkongsi maklumat tersebut dengan anda. Namun begitu memandangkan bidang ini berubah dengan pantas, kemungkinan varian genetik yang tidak diketahui kepentingannya pada masa ini mungkin akan menjadi penting suatu hari nanti. Jika anda menerima penjagaan daripada doktor lain yang percaya bahawa ujian ini boleh digunakan dalam penjagaan dan rawatan anda, bolehlah menghubungi kami pada bila-bila masa dan kami akan kongsikan keputusannya dengan doktor anda.
__[ ]___SAYA TIDAK mahu dihubungi jika varian genetik yang mempunyai potensi implikasi kesihatan ditemui.
__[ ]__SAYA MAHU dihubungi jika varian genetik yang mempunyai potensi implikasi kesihatan ditemui. (Anda akan diberi pilihan samada diberi penerangan atau tidak mengenai perubahan genetik yang kami temui).

_____
Tandatangan Subjek Kajian atau Wakil Sah

Penemuan sampingan signifikan tidak berkait kesihatan
(Pilihan sahaja jika berkenaan, sila keluarkan jika tidak berkenaan)
Jika kami menemui penemuan sampingan yang tidak berkait dengan kesihatan anda tetapi mungkin penting kepada anda atau keluarga anda (contoh: penemuan sampingan tentang bukan paterniti), sila beritahu kami pilihan anda dengan menulis parap nama pada kenyataan berikut:
__[ ]__SAYA TIDAK MAHU di hubungi jika varian genetik sebegitu ditemui.
__[ ]__SAYA MAHU dihubungi jika varian genetik sebegitu ditemui. (Anda akan diberi pilihan samada ingin penerangan atau tidak mengenai perubahan genetik yang kami temui)

_____
Tandatangan Subjek Kajian atau Wakil Sah

*Potensi Implikasi Kesihatan (PIK): Kajian ini melibatkan penyiasatan kepada keseluruhan genom anda. Terdapat lebih kurang 3 bilion pasangan DNA dalam setiap sel manusia yang terbahagi kepada lebih kurang 30,000 gen. Setiap variasi mungkin boleh menyebabkan risiko tertentu kepada sesuatu penyakit. Kebanyakan variasi mempunyai risiko rendah kepada sesetengah penyakit. Namun begitu ada sesetengahnya memberi risiko yang signifikan. Tidak mungkin untuk kami memberitahu dengan tepat semua risiko kerana ia mungkin wujud semasa proses persetujuan ini berjalan, seperti yang telah dinyatakan oleh anda seperti diatas, dimana bila data keseluruhan genom anda telah tersedia.

[Nota untuk penyelidik: Penerangan diatas sesuai untuk jujukan keseluruhan genom. Penyelidik mungkin boleh menukar penerangan untuk disesuaikan dengan kajian yang dijalankan seperti eksperimen berasaskan mikroarray yang menyiasat hanya beberapa ribu atau juta SNPs dan CNVs).

PENDEDAHAN KEPUTUSAN KAJIAN
(Penyelidik perlu memilih satu atau menetapkan jika kedua-duanya berkenaan)

Keputusan Kajian – tidak didedahkan

Kami tidak akan memberi keputusan jujukan keseluruhan [genom dan/atau exome] individu kepada anda. Ini kerana projek ini akan mengambil masa yang lama untuk mengeluarkan maklumat berkaitan kesihatan yang boleh kami tafsirkan dengan tepat. Namun begitu, kami akan beritahu anda jika kami dapati bahawa anda mempunyai, contohnya, penyakit berjangkit yang memerlukan kami melaporkan tentangnya mengikut undang-undang. [nyatakan samada dan bagaimana anda akan meringkaskan keputusan kajian untuk peserta].

Keputusan Kajian- didedahkan

Bilamana kami mempunyai keputusan yang berguna daripada jujukan genom, kami akan menghubungi anda jika anda mahu tahu mengenainya. Kami akan meminta anda datang ke Hospital Universiti Sains Malaysia untuk mengetahuinya. [nyatakan masa yang diperlukan bermula pengumpulan spesimen hingga penerimaan keputusan peserta, jika perlu] Anda akan berjumpa dengan seorang pakar yang akan membantu anda memahami tentang risiko, manfaaat dan limitasi mengenai keputusan kajian anda. Jika anda membuat keputusan untuk menerima keputusan anda, pasukan kajian akan menerangkan maksud keputusan tersebut dan implikasinya kepada kesihatan anda dan keluarga.

PERSOALAN/ ORANG UNTUK DIHUBUNGI

Sila hubungi Penyelidik utama[nama penyelidik utama] di nombor [beri nombor telefon bimbit] dan/atau emel [alamat emel] mengenai perkara berkaitan dengan kajian dan jika anda cedera berkait dengan kajian. Jika anda tidak selesa menghubungi penyelidik utama, anda boleh menghubungi [beri nama kolaborator/penyelidik lain] (kolaborator / ahli kumpulan penyelidik) di nombor [beri nombor telefon bimbit] dan/atau emel [beri alamat emel]

Untuk mendapatkan pandangan bebas mengenai kajian dan hak-hak sebagai peserta kajian anda boleh menghubungi staf dalam Jawatankuasa Etika kajian USM

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KERAHSIAAN

Maklumat perubatan anda akan disimpan oleh doktor dan staf kajian dan tidak akan didedahkan kecuali diperlukan mengikut undang-undang.

Sampel anda tidak dapat mengenalpasti anda (iaitu data peribadi anda tidak akan disimpan bersama sampel anda dan sampel tersebut tidak akan mempunyai nombor kod yang boleh digunakan untuk mengenalpasti anda) atau berkod dan dikira tidak lagi dikenalpasti (apa-apa maklumat yang boleh mengenalpasti anda seperti nama) akan diganti dengan kod dan hanya beberapa orang yang diberi kuasa sahaja mempunyai akses kepada kod ini untuk mengaitkan sampel dan data kepada individu tertentu)

(Pilihan, dalam kes yang perlu laporan, seperti status HIV)
Seperti yang telah ditetapkan oleh peraturan kerajaan [nyatakan peraturan, jika ada], kami perlu melaporkan keadaan anda [nyatakan keadaan] kepada Kementerian Kesihatan [nyatakan pejabat KKM tersebut].

Data yang tidak mengenalpasti anda secara individu daripada kajian ini akan diterbitkan untuk tujuan pengetahuan.

Rekod perubatan anda yang asal mungkin akan dilihat oleh penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori untuk tujuan mengesahkan data . Maklumat perubatan anda mungkin akan disimpan dan diproses dalam komputer.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemindahan data seperti yang dihuraikan di atas.

EDARAN DATA AWAM

(Bahagian ini pilihan dan bergantung kepada penyelidik samada menyerahkan data untuk di kongsi dalam databes)
Data yang diambil daripada kajian ini yang tidak merujuk kepada anda secara peribadi mungkin akan diserahkan ke databes bersama [kebangsaan/antarabangsa] [nyatakan nama databes dan jika akses kepadanya berbayar atau percuma] dan diterbitkan dalam jurnal saintifik. Data yang telah diserahkan kepada databes atau telah diterbitkan dalam jurnal saintifik tidak boleh ditarik semula jika anda menarik diri daripada kajian ini dan meminta supaya semua data anda dibuang dan sampel biologi yang tinggal dimusnahkan. Dalam kes ini perlu difahami bahawa penyerahan ke databes dan penerbitan dalam jurnal saintifik membataskan sesetengah penarikan semula.

Sila beritahu kami pilihan anda dengan menulis parap pada salah satu daripada kenyataan dibawah:
__[ ]__SAYA TIDAK MAHU data yang dihasilkan daripada spesimen biologi saya diserahkan kepada databes.
__[ ]__SAYA MAHU data yang dihasilkan daripada spesimen biologi saya diserahkan kepada databes.

_____
Tandatangan Subjek Kajian atau Wakil Sah

PENYIMPANAN DAN PENARIKAN SAMPEL/DATA KAJIAN

Mana-mana darah atau spesimen tisu yang diambil semasa kajian ini akan disimpan dan dianalisis hanya untuk tujuan kajian ini bagi satu tempoh yang tidak melebihi [nyatakan tempoh masa] tahun, dan akan dimusnahkan selepas kajian selesai. Namun begitu jika anda bersetuju untuk membenarkan kami menyimpan sampel tisu atau darah untuk kajian masa hadapan selepas projek in tamat, anda perlu menandatangani bahagian berkenaan borang persetujuan ini.

Sampel biologi anda akan dimusnahkan dan data anda akan dibuang apabila anda menarik diri daripada kajian.

_____
Tandatangan Subjek Kajian atau Wakil Sah

Jika anda ingin menarik diri daripada projek ini anda boleh menghubungi [nama dan maklumat Penyelidik Utama] di [nama institusi] dan beliau akan memusnahkan sampel yang masih ada dan maklumat bertulis mengenai anda yang telah diambil bagi tujuan kajian ini. Namun begitu, sampel dan data yang dihasilkan daripada sampel anda yang telah di serahkan kepada pusat penyelidikan lain atau diletakkan dalam databes kajian atau diterbitkan dalam jurnal saintifik atau penerbitan lain tidak boleh ditarik semula.

TANDATANGAN

Subjek atau wakil sah perlu menandatangani dan menarikh muka surat tandatangan. [LAMPIRAN B dan LAMPIRAN C]

Borang Keizinan dan Maklumat Subjek Kajian
(Halaman Tandatangan)

Tajuk Kajian: _____

Nama Penyelidik: _____

Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini. Saya telah pun berbincang dan memahami tujuan, prosedur dan risiko yang mungkin dalam kajian ini. Kajian ini telah diterangkan kepada saya dalam bahasa yang saya fahami. Saya telah diberi masa yang mencukupi untuk bertanya tentang kajian dan semua soalan saya telah dijawab dengan memuaskan.

Nama Subjek (>12 tahun),	Tandatangan	Tarikh
_____	_____	_____

Nama Ibu Bapa atau Wakil Sah	Tandatangan	Tarikh
_____	_____	_____

Maklumat Penterjemah
Kajian ini telah diterangkan kepada peserta/wakil sah dalam bahasa [nyatakan bahasa yang digunakan] oleh [nama penterjemah]

Kenyataan Saksi
Saya yang bertandatangan, mengesahkan bahawa peserta yang menandatangani borang maklumat keizinan ini telah diberi penerangan mengenai kajian dalam bahasa yang difahami oleh beliau dan memahami mengenai kajian, risiko dan manfaat menyertai kajian ini.

Nama Saksi Menandatangani	Tarikh
_____	_____

Kenyataan Penyelidik
Saya yang bertandatangan, mengesahkan bahawa saya telah memberi penerangan tentang kajian kepada peserta dan peserta yang menandatangani borang maklumat keizinan ini telah memahami dengan jelas tentang kajian, risiko dan manfaat menyertai kajian ini.

Nama Penyelidik/Tandatangan Individu yang Mengurus Keizinan	Tarikh	Masa Bermula	Masa Tamat
_____	_____	_____	_____

LAMPIRAN C

Borang Keizinan Penerbitan Bahan Subjek Kajian
Halaman Tandatangan

Tajuk Kajian: _____

Nama Penyelidik: _____

Untuk menyertai kajian ini, anda dan wakil sah anda perlu menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya memahami yang nama saya tidak akan dipaparkan dalam bahan yang diterbitkan dan usaha telah dilakukan untuk memastikan kerahsiaan nama saya walaupun kerahsian tersebut tidak dapat dijamin sepenuhnya disebabkan keadaan yang tidak dijangka.
- Saya telah membaca penerangan umum kandungan bahan dan telah melihat semua gambar dan statistik melibatkan saya dan kemungkinan akan diterbitkan.
- Saya telah ditawarkan peluang untuk membaca manuskrip dan meneliti semua bahan yang melibatkan saya tetapi saya telah mengetepikan hak saya.
- Semua bahan yang diterbitkan akan dikongsi kalangan pengamal perubatan, saintist dan wartawan dari seluruh dunia.
- Bahan ini juga akan digunakan untuk penerbitan tempatan, penerbitan buku dan boleh dicapai oleh doktor tempatan dan luar dari seluruh dunia.
- Saya dengan ini bersetuju dan membenarkan bahan tersebut digunakan untuk penerbitan lain seperti yang diperlukan oleh penerbit lain dengan syarat-syarat berikut:
- Bahan tersebut tidak akan digunakan untuk tujuan pengiklanan ataupun sebagai bahan pembungkusan
- Bahan tersebut tidak digunakan luar daripada konteksnya – contoh, sampel gambar tidak digunakan dalam artikel yang tidak berkait dengan gambar tersebut.

_____ _____

Nama Subjek Penyelidikan (Dicetak atau Ditaip) **Nama Singkatan atau Nombor**

_____ _____ _____

Nombor Kad Pengenalan Subjek Penyelidikan Tandatangan Subjek Penyelidikan **Tarikh** (hh/bb/tt)

_____ _____

Nama dan Tandatangan Individu Yang Mengurus Keizinan **Tarikh** (hh/bb/tt)