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

# Registration and Application Form

**For Initial Review and Resubmission**

***(Please fill in or tick whenever appropriate)***

***Please print in A4 size paper***

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| **SECTION I: APPLICATION INFORMATION** |
| 1. **Study Title**
 |  |
| 1. **Type of Submission**
 | * Initial Review
* Resubmission [*Version and date of version must be inserted as a document footer for all resubmissions*]
 |
| 1. **Date of Submission:**
 | <dd/mm/yyyy> |
| 1. **Study Category**
 | * Research involving human participants
* Research involving non-human living vertebrates
* Others (indicate):
 |
| 1. **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:
 |
| 1. **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:
 |
| 1. **Purpose of study**
 | * Academic requirement (Thesis, Dissertation, Training Requirement)
* Independent research work
* Multi-institutional or multi-country collaboration
* Others (indicate):
 |
| 1. **Study Duration**
 | \_\_\_\_\_ months  |
| 1. **Involvement of special populations or vulnerable groups**
 | * Not involving special populations or vulnerable groups
* Children (under 18)
* Indigenous People
* Elderly
* People on welfare/social assistance
* Poor and unemployed
* Homeless persons
* Refugees or displaced persons
* Prison Inmate or other institutionalized individuals
* Subordinates
* Patients currently under your care
* Patients in emergency care
* Patients with incurable diseases
* Others (indicate): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 1. ***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
 |
| 1. ***Study site (where the study will be conducted. Please list ALL sites)***
 | **NAME OF STUDY SITE :** |
| **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
 |
| 1. ***Status of Funding***
 | * In process
* Approved
* No funding (skip 13 and 14)
 |
| 1. ***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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 1. ***Amount of Study Budget***
 | MYR \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Other currency, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
| 1. ***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
 |
| 1. ***Principal Investigator***
 | **Name** <Title, Name, Surname> : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **IC/Passport Number** : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Address** <Institutional Address> : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Office Phone : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Facsimile : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Hand phone : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Email : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. ***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
 |
| 1. **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: |  |
| 1. **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: |
| 1. **Submitted by:**
 | <Title, Name, Surname> |
| Designation |  |
| 1. **PI signature**
 |  |

**Please print your relevant section only**

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| **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: | <with Version Number and Date> |
| Principal Investigator: | <Title, Name, Surname, Matrix No.> |
| 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 | <Title, Name, Surname, Staff No.> |
| Signature and Stamp: | Date of Signature: <dd/mm/yyyy> |
|  |
| **SECTION IIB: SCIENTIFIC REVIEW APPROVAL (for categories 6.2, 6.3 and 6.4)***This section should be signed by the Chair of Research Committee (for categories 6.1 and 6.3) or the Chair of Postgraduate Committee (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: | <with Version Number and Date> |
| Principal Investigator: | <Title, Name, Surname, Staff No.> |
| I confirm that the (RESEARCH/POSTGRADUATE COMMITTEE) 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 plan and specimen collection, processing, storage and data analysis plan including statistical design/framework, as applicable. |
| Issuing committee/office: |  |
| Head of committee/office: | <Title, Name, Surname> |
| Signature and Stamp: | Date of Signature: <dd/mm/yyyy> |
| **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: | <Title, Name, Surname> |
| 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: | <Title, Name, Surname> |
| Signature and Stamp: | Date of Signature: <dd/mm/yyyy> |

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| **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: | <Title, Name, Surname> |
| This is to certify that the **<NAME OF RESEARCH SITE>:**1) Has no local Institutional Review Board/ Ethics Review Committee; and2) Authorizes and acknowledges the JEPeM-USM, located at the Center for Research Initiatives – Clinical and Health Sciences, 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.OR3) 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 | <Title, Name, Surname> |
| Position of Official |  |
| Signature and Stamp | Date of Signature: <dd/mm/yyyy> |