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| **Independent Ethics Committee**  **Ramsay Sime Darby Health Care** | Research Submission Checklist &  Document Receipt Form |

Applicant’s Document Checklist for Submitting an application to Conduct A New Research Project

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| --- | --- | --- | --- |
| Title of Research Project |  | | |
| Protocol Number |  | Sponsor: | |
| National Medical Research Registry (NMRR) ID |  | Note: **NMRR registration is compulsory for all research involving drugs** | |
| Principal Investigator’s (PI) Signature, Name & Stamp |  | PI Institution | |
| Contact No | |
| Study Coordinator(if any) |  | Contact No |  |

**IEC Submission Requirements**

 Please submit

a. One(1) File containing original hard copies of all documents and 1 soft copy of the clinical research submissions (e-mailed to IEC Secretariat). *All sets must be properly organized in a file with dividers.*

b. Three (3) Sets of Abbreviated Research Dossier containing Cover Letter, Application Forms, Protocol, Information Sheet/Consent Form. *Each set must be properly organized in separate files with section dividers.*

 Please submit a cover letter listing all the documents version number and date.

 A one-time application fee of RM 1,500 per research study is charged for the services of IEC to review sponsored research. See below for payment details

 However, it is the prerogative of IEC to waive this fee for non-commercial and non-sponsored research

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Attached?**   |  |  |  | | --- | --- | --- | | Yes | No | NA | | | | **Document ( core language English) submitted**  *Documents in shaded cells are the minimum required for an ethical review by IEC***.** | **Received & checked**  Signed & Dated where applicable |
|  |  |  | Research Application Form |  |
|  |  |  | Evidence of successful NMRR Registration ( For Clinical Trials involving drugs) |  |
|  |  |  | Research Submission checklist |  |
|  |  |  | Study Protocol *(latest version)*   Includes project synopsis   Includes description of the ethical considerations involved in the research.   background information on previous research in the same area  of work that justifies and/or supports the proposal   Please provide a diagrammatic representation (flow chart) of the research protocol |  |
|  |  |  | Participant Information Sheet and Consent Form ( English & other languages where applicable) *The informed consent form and any other written information for subjects should collectively contain the 21 elements stated in the Malaysian Guidelines for Good Clinical Practice under section 4.8 Informed consent for trial subjects* |  |
|  |  |  | Principal Investigator’s & sub investigators’ current curricula vitae  ( signed, and dated); |  |
|  |  |  | Principal Investigator’s & Sub InvestigatorGCP Certificate of Attendance *(Applicable only for clinical trials application.* ***GCP course must be certified by National Committee on Clinical Research****)*  *Sub investigators without GCP certification can be added later after obtaining the recognized GCP certification.* **Only investigators with certified GCP will be approved*.*** |  |
|  |  |  | Certificate of insurance for coverage of subjects in a clinical trial : **Clinical Trial Certificate of Insurance is valid for the period and site** |  |
|  |  |  | Statement from the trial sponsor indemnifying the institution where the research is to be conducted, the investigator and IEC (*dated & signed*) |  |
|  |  |  | Investigator Brochure including available safety information |  |
|  |  |  | Data collection forms to be used in the research project, including but not limited to case report forms. |  |
|  |  |  | Survey Forms/Questionnaires / Diary Card to be provided to subjects |  |
|  |  |  | Subject recruitment procedures including forms, documents, advertisements to be used in recruitment of potential participants e.g. Posters for Advertisement |  |
|  |  |  | Letter of Invitation to Patients |  |
|  |  |  | Letter to Doctors Requesting Referral |  |
|  |  |  | Relevant Publications |  |
|  |  |  | Cheque payment for Industry Sponsored Trials |  |
|  |  |  | Participant Payment / Compensation Details + |  |
|  |  |  | Other Documents: |  |
|  |  |  | Significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account |  |
|  |  |  | E-mail all of the above documents to IEC Secretary |  |

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| --- | --- |
| Date received by IEC Secretariat: |  |
| Received by: |  |
| Documents submitted: | **** Complete ** I**ncomplete, will submit on…………... |
| Comments: |  |

* A one-time application fee of RM 1,500 per research study is charged for the services of IEC to review sponsored research.
* **Application will only be processed upon receipt of full payment.**
* Payment is to be made by cheque or bank transfer.
* Please make the cheque payable/ bank transfer to:

|  |  |  |  |
| --- | --- | --- | --- |
| **Beneficiary Name** | **Bank Name** | **Account No** | **Swift Code** |
| RSD Hospitals Sdn Bhd-SJMC | CITIBANK BERHAD | 0116733013 | CITIMYKL |
| RSD Hospitals Sdn Bhd-SJMC | CIMB BANK BERHAD | 8007337597 | CIBBMYKL |

* Submit the cheque/bank transaction slip together with your applications. Kindly attach the following information with the cheque/ bank transaction slip:

🞎 Full protocol title & No

🞎 PI’s name, department and institution

🞎 Sponsor’s contact person (name and emailing address)