Sila sertakan dokumen yang disenaraikan dibawah dalam format MS. word. Tandakan dengan (√) bagi dokumen yang disertakan. Mohon mengemukan semua dokumen berkaitan dalam salinan lembut ke:

*Please enclose the following documents belowin MS. Word format. Indicate with a (√) if enclosed. Please submit documents in soft copy to:*

**sepukm@ukm.edu.my**

|  |  |  |  |
| --- | --- | --- | --- |
| **Research Title** |  | | |
| **Principal Investigator** | **Name** | **Contact Number** | **Email** |
|  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Investigator’s documents** | | **Explanatory notes** | **Total document** | | | |
| **Investigator** | | **RECUKM** | |
|  | Curriculum Vitae | A summary of the investigator’s education, professional history, and job qualifications or other documentation evidencing the investigator’s qualifications. (Updated CV) | State Number of Curriculum Vitae | |  | |
|  | GCP certificate | The certificate indicating successful participation in a Malaysian GCP workshop. The certificate is issued upon successful completion of the workshop exit exam  Investigator is required to submit his or her GCP certificate unless he or she qualifies for “grandfather” status. The RECUKM will check the validity this claim. | State Number of GCP certificate | |  | |
| **Research documents** | | **Explanatory notes** | **Tick (√)** | | **Tick (√)** | |
|  | Checklist | *UKM-JEP-SS02\_Senarai Semak dokumen (projek percubaan klinikal\_sponsor)* |  | |  | |
|  | Covering letter | A letter accompanying a submission to explain the purpose of the submission |  | |  | |
|  | UKM-JEP-BO01 | UKM-JEP-BO01 - UKM Research Ethics Committee Application Form |  | |  | |
|  | UKM-JEP-BO02 | UKM-JEP-BO02 - UKM Research Ethics Committee Review Form (In Ms. Word Format) |  | |  | |
|  | UKM-JEP-BO08 | UKM-JEP-BO08 - UKM Research Ethics Committee Conflict of Interest Form |  | |  | |
|  | Study Protocol / Proposal | A document that describes the objective(s), design, methodology, statistical considerations, and organization of a research. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents. |  | |  | |
|  | Study Summary/  Synopsis | A brief document that describes the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research.  *Refer: Proposal format\_checklist item that should include in the Proposal* |  | |  | |
|  | Investigator’s brochure | A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (ICH GCP 1.36) |  | |  | |
|  | Information sheet | Document containing information about research intended for prospective research subject. Required in English and Bahasa Malaysia languages | *English* |  | *English* |  |
| *Malay* |  | *Malay* |  |
| *Chinese* |  | *Chinese* |  |
| *Tamil* |  | *Tamil* |  |
| *Others* |  | *Others* |  |
|  | Informed Consent Form | Form to document subject’s consent to participate in the research. Required in English and Bahasa Malaysia languages*.* | *English* |  | *English* |  |
| *Malay* |  | *Malay* |  |
| *Chinese* |  | *Chinese* |  |
| *Tamil* |  | *Tamil* |  |
| *Others* |  | *Others* |  |
|  | Trial indemnification: Insurance / Letter of indemnity | Insurance or letter from sponsor to indemnify (legal and financial coverage) the investigator and institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence. |  | |  | |
|  | CRF/e-CRF | Case report forms contain data obtained during the patient participation in the clinical trial. |  | |  | |
|  | Questionnaires | *Questionnaires contain data obtained during the patient participation.* |  | |  | |
|  | Clinical Trial Agreement (CTA) | A Clinical Trial Agreement (CTA) is a legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property. |  | |  | |
|  | NMRR Registration | Proof of registration (e-mail or letter) with NMRR registration number is required. |  | |  | |
|  | \*Diary card | *Subject Diary contain data obtained during the patient participation in the clinical trial.* |  | |  | |
|  | \*Advertisement | Advertisement for subject recruitment |  | |  | |
|  | \*Approval other EC | *Approval from other EC contain decision and comment about the research.* |  | |  | |
|  | \*A Clinical Trial Import License | *Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX)* |  | |  | |
|  | Hard copies all the above documents | *Hard copies for all document listed above.*  *To be submit when received feedback email from the RECUKM.* |  | |  | |
|  | A copy proof of payment for application RECUKM approval | *Payment to CIMB ISLAMIC BERHAD account no: 8600081140 (UNIVERSITI KEBANGSAAN MALAYSIA)*   |  |  | | --- | --- | | Jenis Permohonan | Kadar (RM) | | Industri (Sponsor)  (Percubaan Klinikal - Sponsor luar UKM) | 1,000.00 |   ***Jenis permohonan bagi Pegawai / Pelajar adalah termasuk warga dan bukan warga UKM***  ***\*Refer Guidelines UKM-JEP-GP02\_Garis Panduan Mengisi Borang Permohonan (Attachment B) at JEPUKM website: https://www.ukm.my/jepukm/*** |  | |  | |

\*If Applicable

Receiver:

…………………………………………………..

Name:

Date: