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| **Research Title** |  |
| **Principal Investigator** | **Name** | **Contact Number** | **Email** |
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| **Investigator’s documents** | **Explanatory notes** | **Total document** |
| **Investigator** | **RECUKM** |
|  | Curriculum Vitae | *Required for all research submitted to RECUKM.*A summary of the investigator’s education, professional history, and job qualifications or other documentation evidencing the investigator’s qualifications | State Number of Curriculum Vitae | State Number of Curriculum Vitae |
|  | GCP certificate  | *Required for Clinical Trial only.*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 | State Number of GCP certificate |
| **Research documents** | **Explanatory notes** | **Tick** | **Tick** |
|  | Covering letter | *Required for all research submitted to RECUKM.*A letter accompanying a submission to explain the purpose of the submission  |  |  |
|  | Study Proposal | Required if no protocol is submitted A brief document that describes the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research. |  |  |
|  | Study Protocol | *Required for all research submitted to RECUKM.*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.  |  |  |
|  | Investigator’s brochure | *Required for clinical trial only*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) |  |  |
|  | Informed Consent Form | *Required for all human subject research* Form to document subject’s consent to participate in the research. Required in English and Bahasa Malaysia languages*.* | *English* |  | *English* |  |
| *Malay* |  | *Malay* |  |
|  | Information sheet  | *Required for all human subject research* Document containing information about a research intended for prospective research subject. Required in English and Bahasa Malaysia languages | *English* |  | *English* |  |
| *Malay* |  | *Malay* |  |
|  | Advertisement  | *Required for clinical trial only*.Advertisement for subject recruitment |  |  |
|  | Trial indemnification : Insurance / Letter of indemnity | *Required for clinical trial only*.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 | *Required for clinical trial only*.Case report forms contain data obtained during the patient participation in the clinical trial. |  |  |
|  | Clinical Trial Agreement (CTA) | *Required for clinical trial only*.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 | *Required for all Clinical Trials involving drugs.*Proof of registration (e-mail or letter) with NMRR registration number is required. |  |  |