**JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)**

**CHECKLIST OF DOCUMENTS REQUIRED FOR CONDUCTING A CLINICAL TRIAL**

Please enclose the following documents in relation to format above. Indicate with a [√] if enclosed

Phase 1 Phase 2 Phase 3 Phase 4

**COMPULSORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents** | | **Researcher**  Please tick (✓) | **Secretariat**  Please tick (✓) |
| 1 | Good Clinical Practice (GCP) certificate |  |  |
| 2 | Investigator’s brochure (IB) - *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)* |  |  |
| 3 | Signed clinical study protocol and amendments |  |  |
| 4 | Sample case report form - *A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.* |  |  |
| 5 | Informed consent form |  |  |
| 6 | Insurance statement - *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.* |  |  |
| 7 | Subject compensation |  |  |
| 8 | Curriculum vitae and relevant documents of qualification of PI and co-PIs |  |  |
| 9 | Certificates of analysis of investigational products |  |  |
| 10 | Decoding procedures for blinded trials |  |  |
| 11 | Respondent information sheet |  |  |
| 12 | All available safety information |  |  |
| 13 | All questionnaires used |  |  |

**IF APPLICABLE:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents** | | **Researcher**  Please tick (✓) | **Secretariat**  Please tick (✓) |
| 1 | Trial Initiation monitoring report |  |  |
| 2 | Advertisement for subject recruitment |  |  |
| 3 | Signed agreement between parties involved |  |  |
| 4 | Shipping records for investigational products |  |  |
| 5 | Pre-trial monitoring report |  |  |
| 6 | Material transfer agreement (MTA) - *For any research involving transfer of biological specimens)* |  |  |