EXPLANATORY NOTES ON DOCUMENT REQUIRED FOR JPEC SUBMISSION

	Document	Explanatory notes
Investigator's documents		
1.	Curriculum Vitae	*Required for all research submitted to JPEC.* A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications (if not submitted within the last 12 months)
2.	GCP certificate	*Required for Interventional 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
Research documents		
3.	Covering letter	*Required for all research submitted to JPEC.* A letter accompanying a submission to explain the purpose of the submission and signed by the Principal Investigator
4.	Application Form to Conduct a New Research Project Involving Human Subjects	*Required for all research submitted to JPEC* An application form filled and signed by the applicant and a signature from the institution director/CEO or medical superintendent is needed.
5.	Applicant's Document Checklist for Submitting an Application to Conduct A New Research Project	*Required for all research submitted to JPEC* A checklist filled up by the applicant stating the type and number of documents submitted.
6.	Study Protocol	*Required for all research submitted to JPEC.* A document that describes the objective(s), background, rationale design, methodology, statistical considerations, and organization of a research.
7.	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)
8.	A summary of the product's characteristics (i.e package insert)	*Required for bioequivalence studies only* Information on the reference product is only submitted when available
9.	Informed Consent Form/ Patient information sheet	*Required for all human subject research* Document containing information about a research intended for prospective research subject Form to document subject's consent to participate in the research. Translation certificate is needed for forms that are translated to another language. The informed consent form and subject information should collectively contain the 24 elements in the **Checklist of minimum requirements in the Informed Consent Form and Written Subject Information**, unless some elements are not applicable
10.	Patients material/ Advertisement	*Required for bioequivalence studies and clinical trial only*. Patient materials and advertisement for subject recruitment that are distributed to subjects
11.	Trial indemnification : Insurance / Letter of indemnity	*Required for bioequivalence studies and clinical trial only*. Insurance or letter from sponsor to indemnify (legal and financial coverage) the investigator, JPEC and institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.