EXPLANATORY NOTES ON DOCUMENT REQUIRED FOR MREC SUBMISSION

	Document	Explanatory notes
Investigator's documents		
1.	IA-HOD-IA form	*Required for all research submitted to MREC.* Investigator's agreement, head of department's and institutional approval to be completed for all Principal Investigators (including Coordinating PI and PI at site)
2.	Curriculum Vitae	*Required for all research submitted to MREC.* A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications
3.	GCP certificate	*Required for all Interventional Study* The certificate indicating successful participation in a Malaysian GCP workshop. The certificate is issued upon passing the workshop exit exam.
4.	Declaration of Conflict of Interest by Principal Investigator	*Required for all research submitted to MREC.* Document to be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest.
Research documents		
5.	Covering letter	*Required for all research submitted to MREC.* A letter accompanying a submission to explain the purpose of the submission and list of documents submitted.
6.	Study Protocol	*Required for all research submitted to MREC.* 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.
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.	Informed Consent Form	*Required for all human subject research* Form to document subject's consent to participate in the research. Compulsory to have in English and Bahasa Malaysia languages. *Optional for other languages (Simplified Chinese/Tamil and etc)*
9.	Patient 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 Compulsory to have in English and Bahasa Malaysia languages. *Optional for other languages (Simplified Chinese/Tamil and etc)*
10.	Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research / genetic, pharmacodynamic / pharmacogenomic / other studies.	*Required if applicable* Document containing information and Form to document subject's consent to participate in *an optional sub-study or optional future research component.* Compulsory to have in English and Bahasa Malaysia languages. *Optional for other languages (Simplified Chinese/Tamil and etc)*
11.	Study Clinical Report Form (CRF) /	*Required if applicable whenever is used* *Document containing all information collected in the study or questions*

	Document	Explanatory notes
	Data Collection Form/Questionnaire	*answered by study participants*
12.	Approval letter from NSCERT	*Required for research that involves stem cells and cell-based therapies* A document / letter stating the NSCERT committee's recommendation to MREC.
13.	Approval letter from NRHDM	*Required for research that involves herbal products* A document / letter stating the National Committee On Research and Development for Herbal Medicine's recommendation / opinion on the safety of the products to be used in the study.
14.	Approval / exemption letter from MDA	*Required for research that involves medical devices.* A document / letter containing the Medical Device Authority's registration / exemption for the device to be used in the study.
15.	Advertisement	*Required for clinical trial only if use* Advertisement for subject recruitment
16.	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.