Essential Documents Required for FIH Submission

No	Document	Explanatory notes
Investigator's documents		
1.	IA-HOD-IA form	*Required for all FIH 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 FIH 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 FIH 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 FIH 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.
5.	Advanced Cardiovascular Life Support (ACLS) Certificate	*Required for all FIH research submitted to MREC.* The certificate indicate investigators are trained in this advanced course which highlights the importance of high-performance team dynamics and communication, systems of care, recognition and intervention of cardiopulmonary arrest, immediate post-cardiac arrest, acute dysrhythmia, stroke, and acute coronary syndromes (ACS).
Research documents		
6.	Covering letter	*Required for all FIH research submitted to MREC.* A letter accompanying a submission to explain the purpose of the submission and list of documents submitted.
7.	Study Protocol	*Required for all FIH 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.
8.	Investigator's brochure	*Required for all FIH research submitted to MREC.* 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)
9.	Investigational Medicinal Product Dossier (IMPD) or Chemistry, Manufacturing and Control (CMC) data	*Required for all FIH study submitted to MREC* Document containing Investigational Medicinal Product Dossier (IMPD) or Chemistry, Manufacturing and Control (CMC) data.
10.	Non-Investigational Medicinal Product (NIMP) dossiers	*Required if applicable* Dossier on the NIMP agents used in the study (eg: challenge agents)
11.	Pharmacy Manual	*Required if available* Reference document for pharmacist in handling of the investigational product
12.	TSE certificates/ statement	*Required if applicable* Document to certify that the Investigation product is manufactured completely from synthetic or manufactured raw materials and does not contain any raw materials produced from or substances derived from animal origin

13.	Informed Consent Form	*Required for all FIH research submitted to MREC.* 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)*
14.	Patient information sheet	*Required for all FIH research submitted to MREC.* Document containing information about a research intended for prospective research subject. Compulsory to have in English and Bahasa Malaysia languages. Optional for other languages (Simplified Chinese/Tamil and etc)
15.	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)
16.	Site Accreditation Document	*Required for all FIH study submitted to MREC* Evidence that site is listed under NPRA's Phase I Unit Inspection & Accreditation Programme
17.	Clinical Trial Insurance	*Required for all FIH study submitted to MREC* Trial Insurance certificate for the study
18.	Checklist for First-in-Human Research Protocol	*Required for all FIH study submitted to MREC* Completed form that indicates the completion of the protocol submitted