

Guidance to Submit Complete Investigators' Documents

	Document Name	Definition of Document
Investigator's documents		
1.	IA-HOD-IA form	<i>Required for all research submitted to MREC.</i> Investigator's agreement, head of departments and institutional approval
2.	Curriculum Vitae (CV)	<i>Required for all research submitted to MREC.</i> A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications. To be completed for all investigators.
3.	Good Clinical Practice (GCP) certificate	<i>Required for all investigators in an Interventional Study</i> 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 (COI) by Principal Investigator	<i>Required for all research submitted to MREC.</i> Document to be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest. This document should include list of ALL existing study investigators, their roles in the study and their respective study sites.

Requirements for Investigators' Document Submission:

		Initial Approval	Amendment
1.	IA-HOD-IA	To be completed for all Principal Investigators (including Coordinating PI and PI at site)	Needed if any addition/changes of principal investigators (including Coordinating PI and PI at site)
2.	Curriculum Vitae (CV)	To be completed for all investigators.	Needed for any additional investigator(s)
3.	Good Clinical Practice (GCP) certificate	Required for all investigators in an interventional study	Needed for any additional investigators in an interventional study
4.	Declaration of Conflict of Interest (COI) by Principal Investigator	To be completed by the Corresponding Principal Investigator on behalf of the study team to declare any conflict of interest.	To be completed by Corresponding PI if any: <ul style="list-style-type: none"> • addition/removal of investigators • change of role • change of investigators' site