Appendix B Documentation Checklist for Submission Package

Please refer to the checklist below to ensure your submissions are complete. Please note that incomplete submissions will not be reviewed until all required material is provided.

APPLICATION

YES	
☐	Application for the Approval of Minimal-Risk/Greater-than-Minimal-Risk Research – **all** sections complete.
☐	I have read the relevant sections of the *MOH Policy for the Conduct of Health Research in Human Subjects*
☐	All signatures obtained: ☐ Principal Investigator ☐ Co-Investigator(s) *(if applicable)* ☐ Head of Division/Department/Course Program [**cannot** be one of the Investigators]

ATTACHMENTS

YES	N/A	
☐	☐	Covering letter from the principal investigator (Applicant) to the vice-chairman of the research committee (with the researcher's Department Head/Chairperson's signature, **mandatory**)
☐	☐	Completed Budget breakdown sheet, if applicable
☐	☐	Referee Data Sheet, if applicable
☐	☐	Informed consent form (English)
☐	☐	Informed consent form (Arabic)
☐	☐	Subject recruitment procedures – advertisements, information letters
☐	☐	Data collection tools – questionnaires, observation forms
☐	☐	List of study centres with contact details, and sample size per centre
☐	☐	CV of Principal Investigator (applicant) and co-investigator(s)
☐	☐	Letters of support from course faculty (for students) or from the Head of department (for staff) *(on official letterhead)*
☐	☐	Letters of approval from other Human Research Ethics Committees *(on official letterhead)*
☐	☐	Letter of acceptance from local investigator responsible for conduct of the research in Bahrain *(for multi-centre studies)*
Documents applicable for Greater-than-Minimal-Risk Research		
☐	☐	Protocol – mandatory
☐	☐	Amendments to protocol/consent documents
☐	☐	Investigator's Brochure/Product Monograph (if applicable, for drug/biologics intervention studies)
☐	☐	Case report forms, Patient diary, Questionnaires, etc
☐	☐	Informed consent/assent form (English)
☐	☐	Informed consent/assent form (Arabic) (with signature and seal by a certified translator/translation service)
☐	☐	Copy of Regulatory permissions (approvals from other Ethics Review Boards, FDA, EMA, etc.)
☐	☐	Agreements/contracts between different parties (sponsor, investigator, study centre, CRO)
☐	☐	NOCs from the Medical Superintendent/Director of the trial site
☐	☐	Insurance policy