Guidance on Required Documents for PHKL REC Submission

Submission Type	Documents Required	Explanatory Notes
New Study Application	PHKL REC Research Approval Application Form	Mandatory application form for all new study submissions to PHKL REC. The form must be completed and signed by the Principal Investigator (PI).
	Study Protocol	Full study protocol including study objectives, methodology, statistical analysis, safety monitoring, and study procedures. The submitted version number and date must be clearly stated.
	Patient Information Sheet (PIS)	Required if participants are involved. The PIS must be written in understandable language and include study purpose, procedures, risks, benefits, confidentiality, voluntary participation, and contact details. Malay and/or other local language versions should be included where applicable.
	Informed Consent Form (ICF)	Required for studies involving participant consent. For paediatric studies involving participants aged 7–18 years old, parental consent form and participant assent form are mandatory.
	Investigator's Brochure (IB)	Mandatory for interventional clinical trials. The IB should contain relevant clinical and non-clinical data regarding the investigational product.
	Relevant Pre-Clinical or Clinical Trial Data	Previous animal studies, published literature, or data from other sites/countries should be submitted if available to support study rationale and safety.
	Decision from Other Ethics Committees	Applicable for multicentre studies or studies previously reviewed by another REC/IRB. Approval letters or comments from other ethics committees should be enclosed if available.
	Clinical Trial Insurance	Mandatory for interventional studies. Insurance coverage should include protection for study participants against trial-related injury.

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	Clinical Trial Agreement (CTA) Draft	Applicable for sponsored or collaborative studies. Draft agreement may be submitted if available during initial submission.
	Curriculum Vitae (CV) of PI and Co-Investigators	Updated and signed CVs demonstrating qualifications, experience, and suitability to conduct the study.
	Good Clinical Practice (GCP) Certificate	Valid GCP certificates for PI and/or Co-Investigators involved in the conduct of the study. Only for interventional study and industry sponsored research.
	Study Annexures	Includes questionnaires, case report forms (CRFs), advertisements, recruitment materials, patient diaries, interview guides, data collection forms, and other study-related materials where applicable.
Study Amendment Submission	PHKL REC Amendment Application Form	Mandatory form for all protocol amendments, administrative changes, or revisions to approved study documents.
	Revised Study Documents	Revised documents must include tracked changes or highlighted amendments with updated document version number and date.
	Amendment Summary / Justification	Clear explanation and rationale for all proposed amendments.
	Supporting Documents	Any revised ICF, PIS, protocol, questionnaire, recruitment material, or investigator brochure related to the amendment.
Protocol Deviation / Violation Submission	PHKL REC Protocol Deviation Reporting Form	Mandatory reporting form for all protocol deviations or violations. Submission should be made within 30 working days upon awareness of the event.

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	Supporting Documents	Relevant source documents, CAPA, deviation logs, correspondence, or explanation letters related to the deviation/violation.
Annual Progress Report Submission	PHKL REC Annual Progress Report	Mandatory yearly progress report for all ongoing approved studies.
	Recruitment Summary	Updated subject recruitment status including number screened, enrolled, completed, or withdrawn.
	Safety Summary	Summary of SAEs, SUSARs, protocol deviations/violations, and other safety-related matters during the reporting period.
	Current Approved Documents	Latest approved protocol version, ICF, and relevant study documents where applicable.
Study Closure Report Submission	Study Closure Report / Final Report	Submitted upon completion or early termination of the study. The report should summarize study outcome, recruitment, safety issues, and study status.
	Publication or Preliminary Findings (if available)	Any publication, abstract, or preliminary results may be submitted if available.
	Confirmation of Data Archival	PI should confirm study records will be archived according to institutional and regulatory requirements.