Barts Health NHS
NHS Trust

Essential documents for the research and development (R&D) process

A list of essential documentation required by R&D to ensure all areas and processes of new research trials are reviewed and accommodated in the validation process

Document	Comment
Protocol (and amendments)	Copy of working protocol submitted to ethics and any subsequent amendments during trial process.
COREC application form + supporting documents.	Full copy of submission document including consent form, P.I.S., PI CV etc.
BLT/QMUL provisional indemnity letter	Essential for ethics approval process.
Sponsorship letter	Confirmation of sponsorship from funder or employing organisation.
Data Protection Form	Data Protection Officer assessment of trial data arrangements. (if study involves BLT patients)
Clinical Trial Authorisation (CTX/DDX etc.)	Where applicable.
Commercial Agreement for Clinical Trial Indemnity	Proof of Indemnity from Pharmaceutical/Industry Sponsor. If applicable.
Financial Agreement / Grants /Funding arrangements	Between sponsor companies / institutions and Trust
Costing	R&D analysis of trial costs and financial breakdown.
Ethical approval letter	Final approval letter from Main Research Ethics Committee including clarification letters.
BLT/QMUL final indemnity letter	Final trust/QM indemnity so that trial can commence.