MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

MQ Health Clinical Research Governance essentials

Stage of governance review	Document (applicable to the research project)
1. Determination of the nature of the project	Preparation of documents for clinical research governance review: • MQ Health Clinical Research Governance Application form. • Project synopsis or full research protocol *(if already prepared).* • Itemised study budget *(if applicable).*
2. Initial MQ Health governance endorsement	• Submission of MQ Health Clinical Research Governance application documents to: clinical.research@mqhealth.org.au • Review by the Clinical Research Executive. • Initial MQ Health governance endorsement.
3. Ethics, insurance, contracts,and service provider approvals	**Ethics:** • Ethics application form using HREA form within FoRA. • A research protocol for clinical research and investigator initiated clinical trials, following the template on the Human Ethics website. • Participant materials using templates on the Human Ethicswebsite. • For sponsored clinical trials, the protocol from the sponsor, Investigator Brochure (non-registered drugs) or Product Information (TGA registered drugs). Submission via MQ online system FoRA. For further information email: ethics.secretariat@mq.edu.au
	Insurance and indemnity: • Standard Form of Indemnity (Medicines Australia). • Insurance certificate.
	Research agreement/s: • Standard research agreement (e.g., funding agreement), or • Clinical trial research agreement (CTRA) Submission to: researchcontracts@mq.edu.au
	Service provider approvals (if applicable) • Macquarie Medical Imaging (MMI): mmi.research@mqhealth.org.au • FMHHS PC2 laboratory: lab.operations@mq.ed.au • Macquarie University Hospital: estimates@muh.org.au, or caroline.odonnell@mqhealth.org.au
	Evidence of Good Clinical Practice training (GCP certificate) for all relevant persons in the last 3 years (for clinical trials)
4. Final MQ Health authorisation	• Final MQ HREC approval. • Evidence of relevant service provider approvals, e.g., MMI, PC2 laboratory, MUH *(if applicable)*. • Evidence of executed research contract/agreement. • Final MQ Health clinical research governance authorisationletter.
5. After final governance authorisation	PI should notify the relevant parties of the start date of the project.