**MQ Health Clinical Research Governance essentials**

<table>
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<tr>
<th>Stage of governance review</th>
<th>Document (applicable to the research project)</th>
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| **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](mailto: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](mailto:).  
  - A research protocol for clinical research and investigator initiated clinical trials, following the template on the [Human Ethics website](https://www.humanethics.org/).  
  - Participant materials using templates on the [Human Ethics website](https://www.humanethics.org/).  
  - 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](mailto:).  
  For further information email: [ethics.secretariat@mq.edu.au](mailto: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](mailto:researchcontracts@mq.edu.au) |
| **Service provider approvals** (if applicable) |  
  - Macquarie Medical Imaging (MMI): [mmi.research@mqhealth.org.au](mailto:mmi.research@mqhealth.org.au)  
  - FMHHS PC2 laboratory: [lab.operations@mq.edu.au](mailto:lab.operations@mq.edu.au)  
  - Macquarie University Hospital: [estimates@muh.org.au](mailto:estimates@muh.org.au) or [caroline.odonnell@mqhealth.org.au](mailto:caroline.odonnell@mqhealth.org.au) |
| **4. Final MQ Health authorisation** | Evidence of Good Clinical Practice training (GCP certificate) for all relevant persons in the last 3 years (for clinical trials)  
  - 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 authorisation letter. |
| **5. After final governance authorisation** | PI should notify the relevant parties of the start date of the project. |