**Flowchart for clinical research governance**

**INVESTIGATOR-INITIATED CLINICAL TRIAL**

**FEASIBILITY AND GOVERNANCE ASSESSMENT**

- Investigator completes and submits clinical research governance application form and project synopsis or full protocol to clinical.research@mqhealth.org.au

  **Initial review by Clinical Research Manager**

- Review by Clinical Research Executive Committee

  **Investigator receives outcome of governance assessment within 5-10 working days of submission**

  - Further changes required
  - Declined
  - Governance endorsement - subject to conditions

  **Investigator responds to comments**

  **End**

**ETHICS, CONTRACTS, INSURANCE AND SERVICE APPROVALS**

- Investigator prepares following ethics related documents:
  - A research protocol following the MQ Health template
  - Ethics application using the NHMRC HREA form
  - Participant materials (eg PICF) on templates from Human Ethics website
  - Any additional supporting documents
  - Submits via Human Research Ethics Management System to HREC

  **Insurance and liability – Clinical Research Manager to liaise with the Macquarie University Insurance Branch if any notification is required**

  **Research contract/funding agreement**
  - Contracts team in Macquarie Research Services
  - Clinical Research Manager to facilitate the process (if applicable)

  **Service provider approvals (if applicable) – eg Macquarie Medical Imaging (MMI), PC2 laboratory, Macquarie University Hospital, etc**

  **Investigator prepares following ethics related documents:**
  - A research protocol following the MQ Health template
  - Ethics application using the NHMRC HREA form
  - Participant materials (eg PICF) on templates from Human Ethics website
  - Any additional supporting documents
  - Submits via Human Research Ethics Management System to HREC

  **Investigator receives outcome of governance assessment within 5-10 working days of submission**

  - Further changes required
  - Declined
  - Governance endorsement - subject to conditions

  **Investigator responds to comments**

  **End**

**FINAL GOVERNANCE AUTHORISATION**

- Final HREC approval

- Contract/funding agreement execution

- Service provider approvals

  - Clinical Research Manager receives final approvals for verification, recommends final governance authorisation and submits for MQ sponsorship approval via DVCR

  **Clinical Research Manager receives MQ sponsorship approval and sends final governance authorisation**

  - All approvals are in place
  - Approvals are incomplete

  **Clinical Research Manager receives MQ sponsorship approval and sends final governance authorisation**

  **Final MQ Health governance authorisation within 1-2 working days**

**MACQUARIE University**