Clinical Trial Governance Authorisation Process

1. Preparation
   a. Prepare ethics and governance applications
   b. Complete Good Clinical Practice Training
   c. Prepare a Data Management Plan
   d. Obtain sign off from Head of School/Centre

2. Review
   a. Seek ethics approval
   b. Submit governance application to Governance Coordinator (can be draft)
   c. Governance Coordinator arranges additional reviews as required

3. Authorisation
   a. Governance Coordinator makes recommendation to Deputy Vice-Chancellor (Research)
   b. Deputy Vice-Chancellor (Research) authorises trial
   c. Governance Coordinator submits Clinical Trial Notification (if applicable)
   d. Governance authorisation granted

Whether you are designing your own, or running a commercially sponsored clinical trial, ensure it is feasible at the University of Tasmania and has the necessary funding prior to embarking on the governance authorisation process.

Research Governance refers to the site specific assessment of a research project and includes:
- Ethics approval
- Legislative and other relevant compliance
- Legal matters, including contracts
- Financial management
- Reporting requirements

At the University of Tasmania, Governance Authorisation of a Clinical Trial is necessary before a trial can commence.

Further information and application and supporting documents can be downloaded from the Clinical Trial Governance webpage. Contact the Clinical Trial Governance Coordinator at any stage: clinical.trials@utas.edu.au

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