Clinical trials conducted in Australia are subject to significant regulatory requirements imposed by a number of different government agencies, including:

- ethical review required under the NHMRC/ARC National Statement on Ethical Conduct in Human research;
- notification or assessment required by the Therapeutic Goods Administration (TGA) including adherence to standards specified by the TGA e.g. Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP);
- state specific legislation for storing drugs, diagnostic testing and privacy.

What is Clinical Trial Governance?
Clinical trial governance refers to the processes used by institutions to ensure that they are accountable for the research conducted at their sites. To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy. Clinical trial governance is also about credentialing and training of researchers and managing institutional risk. When assessing the risk, clinical trial governance is concerned with the quality, safety, privacy, risk management, financial management and ethical acceptability of the research.

Clinical Trial governance encompasses both the ethical review of research and the institutional considerations about undertaking research. Elements of research governance include:

- ethical approval
- compliance with legislation, regulations, guidelines and codes of practice
- legal matters, including contracts, and indemnity/insurance frameworks
- financial management, risk management and site-specific assessment
- institutional policies and procedures for responsible research
- research conduct and managing research misconduct
- management of collaborative research
- reporting requirements

The clinical trial governance framework at the University of Sydney ensures clinical trial research conforms to relevant institutional and National Standards, applicable laws and the Australian Code for the Responsible Conduct of Research.

What does the Clinical Trial Governance Office do?
Clinical Trial Governance provides guidance and support to researchers facilitating the University of Sydney’s obligation to the effective governance of clinical trials involving humans. The Clinical Trial Governance Office is responsible for assessing the suitability of a clinical trial to be conducted at a University of Sydney site and making a recommendation to the DVC-Research. The DVC-Research makes the final decision whether to authorise a clinical trial to be conducted at a University site.

Clinical Trial Governance offers a number of services to researchers conducting clinical trials including:

- online training for researchers conducting clinical trials sponsored by the University and/or taking place at the University at no cost to researchers. The training provides an overview of Good Clinical Practice (GCP)
- tools for researchers to set up and maintain clinical trial records according to GCP requirements including site file, delegation of duties log, subject identification code, and product accountability
- clinical trial insurance provides protection for legal liability to pay damages or compensation as a result of any claim or claims made by research subjects for bodily injury caused when participating in a clinical trial undertaken by the University.
- legal advice through the Office of General Counsel (OGC)

For further information on clinical trials can be found on the Clinical Trial Governance website: [http://sydney.edu.au/research_support/integrity/clinical_trial.shtml](http://sydney.edu.au/research_support/integrity/clinical_trial.shtml) or email clinicaltrialgovernance.research@sydney.edu.au
**Figure I: Summary of the Clinical Trial Governance processes**

### Ethics

- **Pre-HREC approval**
  - Chief Investigator (CI) obtains documentation and instruction from Clinical Trial Governance (CTG).
  - CI drafts documentation and can submit to CTG including legal contracts, SSA, Risk Assessment, Protocol, CVs, HREC approval

- **Post-HREC approval**
  - HREC approval letter and all listed documents in [SSA checklist](#) must be submitted to the clinical trial governance for review and approval where the University is a site for a clinical trial
  - CTN, final and executed Contract, indemnity and insurance (if applicable – pharmaceutical sponsored trials)
  - Site specific PIS/CF and advertising material as well as study specific reporting documents

### Clinical Trial Governance

- **Post-HREC approval and Clinical Trial Governance authorisation**

#### Amendments
- HREC approves, Governance considers impact on the site
- SSA amendment form submitted

#### Safety issues
- HREC approves, Governance considers impact on the site
- Safety form submitted

#### Progress reports
- HREC approves, Governance informed at completion
- Closure form submitted

- HREC final report and closure

- Governance closes Trial CTN with TGA & Insurance broker

- The National Statement and ICH GCP require a process for verifying the conduct of clinical trials through:
  - **HREC Audit**
  - **Governance audit preparation and management**
**Figure 2. Clinical Trial Governance / Site Specific Assessment – Initial Process**

**Getting started**

**Chief investigator (CI) / trial coordinator**
- CI identifies trial staff and co-investigators to undertake clinical trial
- CI develops:
  - ethics application
  - PIS / CF and other ethics documentation

**Clinical Trial Governance Office**
- Assists researchers to conduct clinical trials in accordance with TGA standards (sponsor responsibility of University) by providing:
  - ICH GCP templates
  - Advice on governance matters
  - Access to ARCs training
  - Troubleshoots clinical trial management issues with researchers / project managers

**Sponsor (when USYD)**
- Support and guidance is provided to researchers at the University of Sydney by the HREC and Governance Office to ensure the University meets its clinical trial obligations

**Pharmaceutical Company / contract research organisation (CRO)**
- Pharmaceutical Company/CRO and CI/trial coordinator to identify key personnel:
  - CI/trial coordinator
  - trial monitor
- Provide key project documents to sites:
  - protocol
  - investigator brochure
  - master PICF
  - other information
- Trial monitor obtains site details for:
  - legal documents, insurance, CTN etc.
- Communication plan:
  - study liaison persons
  - delegated responsibilities

**Governance submission**

**CI**:  
- Drafts SSA
- Provide CVs
- Prepares contracts
- Prepares budget
- Drafts Risk Assessment

**Assists researchers to obtain approval to conduct clinical trials on campus**
- Reviews Site Specific Applications and conduct governance assessments
- Reviews standard contracts

**Further information can be obtained from the Clinical Trial Governance website and Ethics website.**

**Pharmaceutical Company / CRO actions:**
- contract
- indemnity
- insurance certificate
- budget
**Figure 3. Clinical Trial Governance / Site Specific Assessment – Post HREC approval to Closure**

**SSA authorisation (to end of study)**

**CI/trial coordinator receives HREC approval letter and approved documents and**
- makes Governance submission to each site
- If approved the PI will receive signed contract, indemnity (if required), signed Governance approval letter
- If involving a CTN, the Governance office will make the submission and provide copy and invoice to be paid
- Submits amendments and progress reports to the HREC and Governance Office
- Submits safety reports to HREC. As well as the Governance Office for those clinical trials sponsored by the University and SAEs / SUSARs occurring on University site

**Governance actions:**
- once notified of HREC approval complete SSA authorisation
- notify the TGA for CTN clinical trials
- List on the clinical trial insurance policy
- For amendments, protocol deviation/violation, progress and safety reports (SUSAR / SAE), liaise with CI/trial coordinator and process the governance forms as required
- assess implications on the site for SSA amendment authorisation
- if required complete audit / monitoring for clinical trials
- Report any protocol violations to the HREC

**Pharmaceutical company / CRO actions:**
- receive standard SSA authorisation letter
- register CTN with TGA
- process amendments and reports throughout the trial
- Undertake monitoring and audits
- Train site staff on study protocol and ICH GCP
- liaise with site staff
- register & update the study with clinicaltrials.gov

**Study closure**

**CI / trial coordinator actions:**
- Submit to HREC the final report
- If CTN, submit closure form to Clinical Trial Governance
- archive all trial related documentation for period determined by State Records Act

**Governance actions:**
- receive a copy of the final study closure report or site closure report from PI/trial coordinator
- send an acknowledgement for the report to the site CI/trial coordinator
- close the CTN with TGA (if required)
- update the clinical trial insurance

**Pharmaceutical company / CRO actions:**
- receive a copy of the final study closure report or site closure report from the CPI/trial coordinator
- receive a copy of the governance acknowledgement of the report from the CI
- close CTN with TGA
- close the study on clinicaltrials.gov

Further information can be obtained from the **Clinical Trial Governance website** and **Ethics website**.