Clinical Trials: Summary of Research Governance Processes for Initial Review

The research governance review process for clinical trials may involve (but is not limited to) assessment of the following:

* Compatibility of the research project with the CALHN’s research aims
* Feasibility of the research project with consideration of the required resources at CALHN (e.g. financial, human resources, infrastructure)
* Expertise and experience of researchers, and ensuring that training for research staff is undertaken as required
* Compliance of the research project with relevant laws, policies and guidelines (e.g. radiation safety, confidentiality, intellectual property, biosafety and licensing standards)

The process of clinical trial governance review is set out in following charts.

Please note: these timelines are a guide only.

**Applicant submits CDA**

Review of the CDA is conducted against the following criteria, and checklist found at <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/research-governance/clinical-trials-2/> under the “Confidentiality Disclosure Agreement (CDA)” tab:

* “Confidentiality Agreement Checklist”
* “Parties and Signatories to a CALHN Research Agreement”
* Whether or not it is a Mutual CDA
* Ensure that the CDA is not signed by the PI on behalf of the organization
* Ensure the CDA is in line with the Governing Law of South Australia
* Check any third party beneficiary clauses (if CRO is used)
* Check effective date of the agreement
* Check Institution Party name and multi-site details are correct
* Check execution section is correct for each party

Estimated time frame for CDA first review is 24/48 hours, however may be subject to any potential alterations that may be required

Once the CDA review is complete and correct, the CDA will be presented to the Manager, CALHN Research Office for review and sign off.

**Applicant submits CTRA**

**Please submit a draft of the completed CTRA in word document format for initial review.**

Review of the CTRA is conducted in line with the following criteria, checklists and guidelines found at <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/research-governance/clinical-trials-2/> under the “Clinical Trials Research Agreement (CTRA)” tab:

* “Clinical Research Agreement Guidelines”
* “Medicines Australia and Medical Technology Association of Australia Commercial Research Agreement – Standard Form Checklist”
* “CRG and Phase IV Clinical Trial Research Agreement – Standard Form Checklist”
* “SEBS Schedule 7 and 4 Special Conditions to a Clinical Research Agreement”
* “Parties and Signatories to a CALHN Research Agreement”
* “Form of Indemnity Agreement for Clinical Trials Checklist”
* “Patient Information and Consent Form Guidelines”
* “Invoicing Details and Fee Schedule for Governance Applications”
* “Clinical Trial Budget/Schedule 2 Preparation, Invoicing and Payment Guidelines”
* Financial review

**Applicant submits SSA**

Review of the SSA is conducted in line with the following criteria, checklists and guidelines found at <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/research-governance/clinical-trials-2/> under the “Site Specific Assessment (SSA)” tab:

* Final collation and review of submission documents
* “Site Specific Assessment (SSA) Form Guidelines”
* “Full Site Specific Assessment Checklist”

Estimated time frame for review of complete, valid SSA is 7 days, however may be subject to any potential alterations that may be required.

Once the SSA review is complete and correct, the SSA package will be presented to the Director of Medical Services for review and sign off.