Clinical Trials Insurance

Is your trial a Clinical Trial?

For the purpose of this specific insurance cover, a Clinical Trial is defined as:

> *Any research study, healthy volunteer study or observational study undertaken to evaluate the effects on health outcomes, that complies with the statutory requirements or guidelines of the relevant person, authority, department or public or private body in the country in which the trial takes place.*

Which Clinical Trials are not covered?

Clinical Trials involving Creutzfeldt-Jakob disease or Hepatitis Non A, HIV, AIDS, ARC or similar syndrome or condition are not covered.

The following Clinical Trials are also **EXCLUDED** unless specifically agreed to by UQ's Clinical Trial insurer:

- those involving patients aged 5 and below;
- any pregnancy-related Clinical Trial;
- any overseas (non-Australian) Clinical Trial where local insurance cover is required.

Which Clinical Trials need to complete the attached form for insurance declaration?

- ☑ Any Clinical Trial involving patients aged 5 and below;
- ☑ Any pregnancy-related Clinical Trial;
- ☑ Any Clinical Trial taking place overseas where local insurance cover is required;
- ☑ Clinical Trial Notification (CTN) scheme;
- ☑ Clinical Trial Exemption (CTX) scheme.

The documents requested in the attached form must be provided. Further information may be requested depending on the nature of the Clinical Trial.

Risk assessment

The completion of a risk assessment is mandatory for all clinical trial research.

What is covered?

The University and its subsidiaries have cover for liability associated with Clinical Trials where:

- a research subject suffers a bodily injury; or
- a research subject suffers property damage; and
- the injury or damage arises from a Clinical Trial covered by the Policy.

Who is covered?

The Clinical Trial cover responds to the potential liability of almost everyone associated with Clinical Trials undertaken by UQ and its subsidiaries, when they are acting within the scope of their duties in connection with the trial, within the terms of any protocol, and with the prior informed written consent of the research subjects.

Overseas trials

If you are undertaking a Clinical Trial in an overseas country, that country may require you to take out a local policy with a local insurer.

Insurance Services can assist you in determining if a local insurance policy is required and arrange for it to be obtained. This process can take several weeks.

If a local insurance policy is taken out, UQ's general Clinical Trial insurance will sit as additional cover in excess of the local policy.

You will need to seek your own legal advice on the other regulatory requirements of the country in which you are going to conduct this trial.

Clinical Trial amendments

Any amendments that change the answers to the information you have provided (including the duration of the trial) should be emailed to insurancerenewals@uq.edu.au.

Insurance Services

The University of Queensland
Level 4, JD Story Building
St Lucia Campus
Brisbane QLD 4072 Australia

T +61 7 3365 3075

E insurance@uq.edu.au
W https://governance-risk.uq.edu.au/

Clinical Trial Declaration for insurance purposes – ALL SECTIONS MUST BE COMPLETED

Ethics Approval Number:					
1.	**Ethics Approval** Which institution/s granted ethics approval?				
	Clinical Trial Administrator Who is administering the funding for the clinical trial?				
	Funding (if applicable) Who is funding the trial?				
	Is there an agreement in place between collaborators for this Clinical Trial? Please include a copy.	Yes ☐ No ☐ Not Applicable ☐			
2.	**Clinical Trial Title & Description** Provide the trial name and a brief description (short paragraph). Please include a copy of any **Protocol**.				
3.	**UQ Role** What is UQ's role in the clinical trial? e.g. Sponsor, principal investigator, principal local investigator for an overseas trial (responsible for all Australian sites), investigator (for own site only), funder only, supplier of products only, researcher only (no volunteer contract)				
4.	**School / Department:** Which School / Institute is involved in the trial?				
5.	**Principal Investigator:** Principal Investigator's Details.	**Name:**		**Position:**	
		Email:		**Phone:**	
6.	**Sponsor** (if applicable): What is the name of sponsor, their insurer and policy limits?				
7.	**Indemnity:** Is an indemnity provided by the sponsor?	Yes ☐ No ☐ Not Applicable ☐			
8.	**Granting Body** (if applicable): Who is the granting body for the non-sponsored trial?				
9.	**Phase of Clinical Trial:** At what phase is the clinical trial? (Phase I, II, III or IV)				
10.	**Target Participant Numbers:** What is the number of participants anticipated to be involved in the trial during the next 12 months?				
	UQ Responsibility: Of the number of participants anticipated to be involved in the trial during the next 12 months, how many will UQ be responsible for?				
	What is the **target group** of volunteers (eg children or the elderly)?				
11.	**Target Participants For Whole Trial Period:** What is the number of participants anticipated to be involved in the whole trial?				
	UQ Responsibility: Of the number of participants anticipated to be involved in the whole trial, how many will UQ be responsible for?				
12.	**Number of UQ Sites:** What is the total number of UQ clinical trial sites?				
	Overseas Sites: What is the total number of UQ clinical trial sites overseas? Please include locations (city, country).				

	For overseas sites, have you determined and complied with any **local requirements**, including insurance requirements? If you are collaborating with an overseas local entity, please attach the contract with the Indemnity and Insurance clause highlighted.	Yes ☐ No ☐ Not Applicable ☐
13.	**Invasive Nature of Trial:** Provide details of any invasive procedures to be used during the trial.	
14.	**Start Date:** What is the start date of the trial?	
15.	**End Date:** What is the expected end date of the trial? Please note: Insurance cover will only be in place **until this date**. Any trial amendments require UQ Ethics approval and notification to insurancerenewals@uq.edu.au	
16.	Please include a copy of the **Informed Consent Form** for the trial.	
17.	**Name of Drug / Device**	
18.	**Dosage of Drug**	
19.	**Trial - Full Description:** Refer to Protocol as appropriate. Please include references to risk events.	
20.	**CTN/CTX trials:** Is the trial a CTN or CTX trial?	Yes ☐ No ☐

I declare this document is true and correct to the best of my knowledge:

_____ _____

Signature - Principal Investigator **Date**