

Insurance for Clinical Trials

Governance and Risk Division - UQ Insurance Services

UQ and its subsidiaries have cover for liability associated with human research studies (including clinical trials) conducted by them or on their behalf where:

- **a research subject suffers a bodily injury; and**
- **the injury arises directly from a study covered by the policy.**

For the purpose of this specific cover, clinical trials are considered to be:

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.

Clinical trial insurance responds to the potential liability of almost everyone associated with clinical trials undertaken by UQ and its subsidiaries, so long as they are acting within the scope of their duties in connection with the clinical trial, within the terms of any protocol, and with the prior informed written consent of the research subjects.

This includes employees of all descriptions, students whilst under the direction of UQ, any sub-contractor, doctor, etc.

The cover extends to studies conducted anywhere in the world unless local insurance cover is required - see information below regarding when a Declaration is required for cover to be available (for geographical and other reasons).

The requirement to obtain ethics approval for clinical trials is managed by the [UQ Office of Research Ethics](#).

Is my research study a 'Clinical Trial'?

To be considered a Clinical Trial within the above definition (i.e. for insurance purposes) a research study must:

- Be a human research study; and
- Require UQ human ethics review; and
- Involve either:
 - A drug, device or health intervention; or
 - An observational or educational study to evaluate the effect of identified factor(s) on health outcomes, or the association of identified factor(s) with health outcomes.

This can result in a wide range of studies being considered a Clinical Trial for insurance purposes, where they might not typically be thought of as a 'clinical trial' in other contexts. For example, Clinical Trials may (where the study meets the above criteria), include:

- Epidemiological surveys
- Population level studies
- Psychophysiological outcome studies
- Blood sampling studies (e.g. seroprevalence)
- Parenting intervention evaluations

If you are not sure if your research study is considered a Clinical Trial for insurance purposes, please read the FAQs below. If you still need further guidance, please contact [Insurance Services](#).

Declaration and Notification of clinical trials

To ensure appropriate insurance coverage, many Clinical Trials must be either Declared or Notified to UQ's insurer.

The following clinical trials must be specifically declared (for approval) and accepted by the University's insurer prior to the commencement of the trial:

- Trials involving patients aged 2 and below (unless only observational / non-invasive, data analysis or data gathering / survey);
- Trials involving pregnant participants (unless only observational / non-invasive, data analysis or data gathering / survey); and
- Trials being undertaken overseas (non-Australian trials), where local insurance cover is required.

For these trials the [Insurance for Human Research Studies - Declaration for Approval](#) must be completed and submitted to Insurance Services.

For many other Clinical Trials, to ensure no prejudice to insurance cover, the [Insurance for Human Research Studies - Notification](#) must be completed (after ethics approval is sought) unless:

- The trial is Low or Negligible Risk per UQ guidance on [Human Ethics](#) applications (these trials do not need to be Notified or otherwise reported to Insurance Services); or
- The trial is excluded from cover (see further below).

Refer to the flowchart at **Appendix 1** for guidance on when a Clinical Trial needs to be either Declared or Notified.



Amendments to research/clinical trials

The answers provided in a Notification or Declaration should be updated where a change substantially impacts on the risk profile for the research/trial. This may occur with any Clinical Trial, but be particularly relevant to an adaptive Clinical Trial.

For Notifications - this includes a significant increase to the number of participants, a significant extension to the end date, a change in target group of participants, or any substantive change to the treatment delivered as part of the research/trial.

For Declarations - this includes *any* increase to the overall number of participants, an increase in participants aged 24 months and under, *any* extension to the end date, a change in target group of participants, or *any* substantive change to the treatment delivered as part of the research/clinical trial.

To update your submission:

1. Click [HERE](#) to open the 'Insurance for Human Research Studies - Notification' **OR** click [HERE](#) to open the 'Insurance for Human Research Studies - Declaration for Approval'.

Follow steps 2 to 4.

If shown a list of 'My Responses', these are your submissions that have been partially completed but not submitted. (These may be submissions you elected to 'Save and Exit' to complete at a later stage).

To update a notification or declaration, click 'START NEW RESPONSE' and follow the steps below.

2. Complete Question 1. (your contact details)
3. At Question 2. select 'Update to a previous submission', click 'Next'
4. Complete the following questions: RESEARCH/CLINICAL TRIAL IDENTIFICATION and UPDATED DETAILS, click 'Finish'

Mandatory Risk Assessment

The completion of a [Clinical Trials Risk Register Template](#) is required for clinical trial research in accordance with the Clinical Trial Governance Procedure (PPL 4.20.03). The risk assessment may need to be repeated upon occurrence of an adverse event.

You do not need to provide a copy of your completed risk assessment and management plan (RAMP) to UQ Insurance Services. Per [PPL 4.20.03 Clinical Trials Governance](#), the approved RAMP must be submitted to Research Ethics and Integrity as part of the ethics approval or ratification.

Excluded Clinical Trials

UQ's Clinical Trial insurance does not cover claims involving Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob disease (CJD), Hepatitis Non A, HIV, AIDS, ARC or similar syndromes or conditions. Please contact Insurance Services to discuss whether or not cover can be arranged for any planned trials impacted by this exclusion.

Clinical trial claims are also not covered where:

- they relate to a breach of/failure to comply with the Protocol, or
- the trial was performed without the informed written consent of research subjects (unless the trial is non-interventional and use of patient data is consistent with local regulatory requirements).



Overseas Sites

For Clinical Trials with overseas sites, there are some issues which you should be aware of. While the cover offered by UQ's insurer is global (unless local insurance cover is required), you must be aware of local legislation and clinical trials insurance requirements in each state/territory/country where UQ is responsible for the conduct of a trial/acting in the role of sponsor. UQ's [Office of Research Ethics](#) can assist with obtaining confirmation from UQ Legal Services of the overseas requirements.

Many states/territories/countries have specific legislation which means that the only compliant solution is one which involves the purchase of a local policy. The insurance requirements in some of these areas can be extremely onerous. The local policies will match the legislated scope of cover required, but also pick up other mandated requirements, such as being in the local language and incurring local insurance taxes.

Insurance Services is able to assist with the purchase of local policies in overseas states/territories/countries. An additional cost may apply and will vary by location, reflecting the nature of local legislation, the type, size and duration of the trial. Any additional cost is payable by the relevant UQ business unit.

To ensure you have a fully compliant clinical trials solution in place for overseas trial sites, please email Insurance Services insurance@uq.edu.au

Potential Clinical Trial Claims

[UQ Insurance Services](#) and the [UQ Office of Research Ethics](#) should be advised immediately of any potential claim. Failure to promptly notify the University's insurer of a claim may prejudice cover.

Reporting Adverse Events

The below table identifies when an adverse event needs to be reported to Insurance Services for notification to UQ's clinical trials insurer:

	Type of Event	When to Notify
AE	Adverse event (may be considered related or unrelated to the trial)	Only notify when related to trial or there is a suggestion that compensation is sought or lawyers are to be involved
SAE	Serious adverse event (may be considered related or unrelated to the trial)	Only notify when related to trial or there is a suggestion that compensation is sought or lawyers are to be involved
SUSAR	Suspected Unexpected Serious Adverse Reaction (SUSAR) - serious reaction which was unexpected and is thought to be related to the clinical trial	Notify immediately/ASAP

NOTE: Adverse events do not need to be reported to Insurance Services where they relate to an observational cohort (participant not being treated as part of the research study).

FREQUENTLY ASKED QUESTIONS

Q: What is the difference between Declaring and Notifying a Clinical Trial?

A: Both processes collect information for UQ's clinical trials insurer. They are separate processes, as different information is needed depending on the nature of the Clinical Trial. The flowchart at Appendix 1 provides guidance on when you need to complete either a Notification or Declaration.

Q: Do I need to Notify or Declare a study which has only been ratified by UQ?

A: Yes, both studies which have received ethics approval from UQ and studies which have been ratified by UQ are considered Clinical Trials being conducted by UQ.

Q: Another organisation is providing clinical trials insurance cover for my research study, do I still need to Declare or Notify it to UQ's clinical trials insurer?

A: Please seek advice via [UQ Insurance Services](#) based on the specific circumstances of your research study.

Q: Is a verbal survey, data collection study or observational study still considered a Clinical Trial?

A: Yes, if your study evaluates the effects of identified factor(s) on health outcomes of participants. However often these studies will be classed as [low or negligible risk](#), so may not need to be Notified or Declared to UQ's insurer (refer to the flowchart at Appendix 1).

Q: My research study is classed as low or negligible risk, or is exempt from ethics review - do I still need to Notify or Declare it to UQ's insurer?

A: The flowchart at Appendix 1 provides guidance on when you need to complete either a Notification or Declaration.

Q: Are animal studies considered Clinical Trials for insurance purposes?

A: No, only human research studies. Animal studies do not need to be reported to UQ's insurer.

Q: My research study measures health parameters, but does not evaluate the effect of identified factor(s) on health outcomes - is this still considered a Clinical Trial for insurance purposes?

A: No, research studies which do not evaluate effects of identified factors(s) on health outcomes (or association of identified factors with health outcomes) are not considered a Clinical Trial for insurance purposes, and do not need to be reported to UQ's clinical trials insurer.

This summary has been prepared for general reference only. Nothing contained herein prevails over the terms, conditions and exclusions of the policy. This fact sheet is for internal UQ use only (e.g. by Staff or students or others engaged in the conduct of UQ clinical trials on behalf of UQ). It should not be provided to third parties outside UQ.

For further details, please contact:

The University of Queensland
insurance@uq.edu.au
governance-risk.uq.edu.au



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APPENDIX 1: Do I need to Notify or Declare my human research study to UQ Insurance Services?

