THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

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Insurance for Human Research Studies

Governance and Risk Division - UQ Insurance Services

UQ and its subsidiaries have cover for liability associated with human research studies (including clinical trials) undertaken to evaluate the effects on health outcomes 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.

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).

Where UQ is involved in a human research study sponsored by a third party, UQ should seek confirmation that the third party sponsor holds clinical trials insurance for that study (including a certificate of currency for that insurance cover).

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 requirement to obtain ethics approval for clinical trials is managed by the UQ Office of Research Ethics.

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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 human research studies

To ensure appropriate insurance coverage, many human research studies must be either Declared or Notified to UQ's insurer.

The following human research studies (which meet the insurance definition of a 'clinical trial') must be specifically declared (for approval) and accepted by the University's insurer prior to the commencement of the trial:

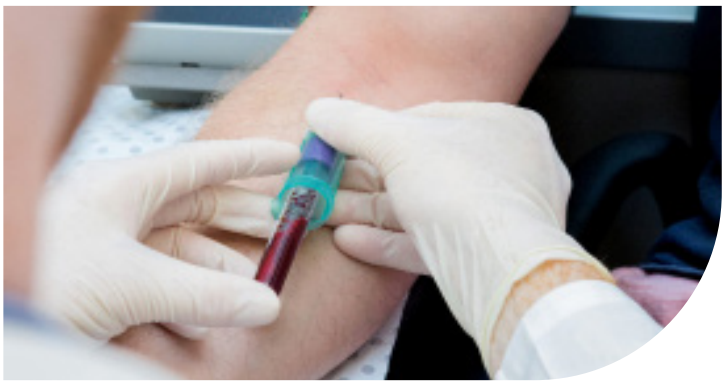
- Studies involving patients aged 2 and below (unless only observational / non-invasive, data analysis or data gathering / survey);
- Studies involving pregnant participants (unless only observational / non-invasive, data analysis or data gathering / survey); and
- Studies being undertaken overseas (non-Australian/NZ trials) (a local insurance policy may be required).

For these studies the Insurance for Human Research Studies - Declaration for Approval must be completed and submitted to Insurance Services.

For other studies (which meet the insurance definition of a 'clinical trial'), to ensure no prejudice to insurance cover, the Insurance for Human Research Studies - Notification must be completed (after ethics approval is sought) unless:

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

Refer to the flowchart at **Appendix 1** for guidance on when you need to complete either a Notification or Declaration.



Amendments to human research studies

The answers provided in an Insurance for Human Research Studies - Notification or Insurance for Human Research Studies - Declaration for Approval should be updated where a change substantially impacts on the risk profile for the research/trial. This may occur with any study, 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. 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 Clinical Trial Governance Procedure, the approved RAMP must be submitted to Research Ethics and Integrity as part of the ethics approval or ratification.

Excluded human research studies/Claims

Human research studies involving Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob disease (CJD), Hepatitis Non A, HIV, AIDS, ARC or similar syndrome or condition are not covered under the policy. If you are planning to conduct a human research study (which meets the insurance definition of a 'clinical trial') involving one of these conditions, please contact Insurance Services as early as possible to explore whether or not separate insurance cover can be arranged.

Claims are also not covered where they relate to these conditions (e.g. transmission of these conditions in the context of a study), to a breach of / failure to comply with the Protocol, or where the study was performed without the informed written consent of research subjects (unless the study is non-interventional and use of patient data is consistent with local regulatory requirements).

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Overseas Sites

For human research studies 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 insurance requirements in each state / territory / country where UQ is responsible for the conduct of a study / acting in the role of a sponsor. UQ's Research Ethics and Integrity (REI) can assist with obtaining confirmation via 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 (payable by the business unit conducting the study). This cost will vary by location, reflecting the nature of local legislation, the type, size and duration of the study. To ensure you have a fully compliant insurance solution in place for overseas sites, please email Insurance Services insurance@uq.edu.au

Potential Claims

UQ Insurance Services and the UQ Office of Research Ethics should be advised immediately of any potential research study/clinical trial 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 study)	Only notify when related to study 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 study)	Only notify when related to study 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 study	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.

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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?

Q1. Is your human research study a "Clinical Trial" for the purpose of UQ insurance cover?

Refer definition and FAQs on previous pages.

NO → No further action required.

YES ↓

Q2. Does your research study involve sites outside Australia and New Zealand?

YES → Please complete an online Declaration and wait for confirmation regarding whether or not additional insurance is required before commencing the Clinical Trial.

NO ↓

Q3. Does your research study involve pregnant participants or participants aged 2 and below?

YES ↓

Q4. Is your research study only observational, non-invasive, data analysis or data gathering/survey?

NO → Please complete an online Declaration and wait for Insurer approval before commencing the Clinical Trial.

YES ↓

NO ↓

Q5. Is your research study classed as negligible or low risk (for insurance purposes, this includes trials for which an exemption from ethics review has been granted)?

YES → No further action required.

NO ↓

Q6. Is the only reason your study is not considered Low or Negligible risk due to phlebotomy/blood sampling?

NO → Please complete an online Notification.

YES ↓

No further action required, (for insurance purposes this is classed as low risk)

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