

Insurance Cover For Clinical Trials/Investigative Study

A “clinical trial” is defined as:

“Human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.”

It can involve testing a drug, a surgical procedure, other therapeutic procedures/devices, a preventive procedure, or a diagnostic device/procedure.

In a University context, research can be so broad that a wider definition of a Clinical Trial is required. As such, the Macquarie University insurance policy wording, defines Clinical Trial as any **‘Investigative Study’**. This is a benefit as any study where human research ethics approval and trial protocols for research subjects are required will be included in the cover.

What is covered?

All investigative studies, approved by Macquarie University approval processes, are covered under the insurance program. However, the following studies require greater disclosure to the Insurers. These are outlined in the table below.

Intervention scale Participant/ Nature of Study	Observational*	Interventional or Invasive #
Pregnant women	Covered	REFER
Children ≤ 5 years	Covered	REFER
Involving Blood Plasma or whole blood products	N/A	Collection – Covered Exchange - REFER
Human Phase 1 Trial	REFER	REFER
Study <u>conducted</u> overseas	REFER	REFER

* *Observational studies: the monitoring and, or review of participants without:*

- *provision of direction or instruction to participants*
- *change or alteration to the participants environment*

Interventional or invasive studies: studies where participants are:

- *provided direction or instruction on how to act or complete a task*
- *undergo a procedure or therapy*
- *provided with medication or a medical device, or*
- *where the participants environment has been materially altered.*

Who is covered?

- Any present MQ staff/employee or past staff/employee for duties undertaken whilst employed by the University;
- Any student under the supervision of MQ personnel or past MQ student for activities undertaken whilst a student of the University;
- Any volunteer or persons borrowed by MQ whilst conducting duties within the scope of the instruction from the University;
- Honorary clinical staff of Macquarie University, declared to Underwriters and are within the insurance referral criteria, for claims arising out of a Trial covered by the Policy;
- Any sub-contractor doctor/consultant physician/hospital (including MUH) or contract research organisation or nurse who will be performing work for MQ directly relating to the MQ Trial covered by the Policy;
- Contractors, including contract lecturers, whilst acting within the scope of their duties;
- Ethics Committee;
- Any independent Data Monitoring Committee or its members and/or and Scientific Advisory Committee or its members and/or any Trial Specific Management Committee and its members and/or any Operations Executive Committee or its members and/or any Trial Related Committees.

When to let MQ Insurance know?

Once researchers are able to determine the need for either Ethics approval or the need for a participant protocol, it is wise to do a check to see if we need to disclose to the Insurers:

1. The nature of the study, and or
2. The involvement of honorary staff and or third parties and facilities.

Should an adverse event occur, notify the insurance team as soon as practicable. This policy is a 'claims-made' policy, which means you need to let us know about an event within a reasonable timeframe in order for us to draw on the cover.

If you are not sure, contact us and we will help: **Insurance.MQ@mq.edu.au**