Australian Government

Australian Clinical Trials

Frequently Asked Questions: Indemnity and insurance arrangements for clinical trials in Australia.

Insurance and indemnity requirements vary across Australia and between institutions. These FAQs provide an overview of general requirements but do not constitute insurance or legal advice.

In 2014, NHMRC engaged Rallis Legal to review indemnity and insurance arrangements for clinical trials in the public and private sectors. The report outlines the indemnity and insurance arrangements (as at May 2014) and concludes that indemnity and insurance arrangements should not be a barrier to a national approach for ethical and research governance.

The following FAQs, which are informed by the report, have been developed to inform researchers involved in clinical trials on requirements for indemnity and insurance arrangements relating to conducting clinical trials in Australia.

Definitions:

- **HREC**: Human Research Ethics Committee, including its individual members.
- **Insurance:** A policy taken out by an individual or individual organisation to cover their liabilities.
- **Indemnity**: An indemnity is a promise by one party to another that it will cover a loss arising from an event that happens to the other party.
- **Private sector**: An organisation (whether run for or not-for profit) or individual not covered by a State or Territory insurance or indemnity scheme.
- **Reinsurance**: An arrangement entered into by an insurance provider, whereby it seeks its own insurance against certain events, such as it having to pay out a large number of large insurance claims – for example after a natural disaster.
- **Self-insurance**: Self-insurance is where an organisation or individual sets aside and manages their own funds to cover their liabilities, rather than buy an insurance policy from an insurance provider or seek an indemnity for a third party. Except for large entities – such as States and Territories – self-insurance is *not* suitable coverage for clinical trial sponsors, sites or investigators.

GENERAL

What is the difference between insurance and indemnity cover?

An **insurance policy** is generally taken out by an individual or institutions to cover *their* own risks or liabilities. The person who takes out an insurance policy is called the **insured**.

For example, General (or Public) liability insurance covers risks that occur on an institution's property or at events organised by the institution; while product liability

insurance may cover risks arising from the use of a medicine or medical device. Professional liability insurance covers risks that arise from giving or performing a professional service such as medical advice or treatment.

The insured must pay a premium for the cover and, except in rare circumstances, this premium is determined on the risk-profile and claim history of the institution or individual and the types of activities cover is being sought for.

An **indemnity** is a promise by one party to another that it will cover a loss arising from an event that happens to the other party. The party covered by an indemnity arrangement is called the **indemnified**.

If cover is provided by way of an indemnity or managed fund or scheme arrangement, the relevant State or Territory underwrites the risks, although the fund or scheme is often supported by reinsurance arrangements to mitigate the State's or Territory's exposure. Unlike insurance arrangements, the cover provided under an indemnity or managed fund arrangement may be discretionary.

How can I find out details about my insurance cover? Or the insurance cover of another party?

Important insurance details are recorded in a Certificate of Insurance, for example the types of liabilities covered and any monetary limit for a single event.

Many insurers require an insured individual or organisation to not disclose specific details of their insurance cover, including the premium paid. However, you can request a Certificate of Currency from an insured as evidence that their insurance is current and meets certain conditions.

Why do clinical trial sites require insurance and/or an indemnity?

Indemnity and insurance arrangements are taken out to protect the clinical trial site against liabilities that it may incur in the course of its clinical trial activities. In the case of insurance, the **insured** will typically be the institution, its directors and employees (including researchers).

Although clinical trial participants are neither **indemnified** or **insured** parties, insurance and indemnity arrangements ensure that an institution or sponsor is able to compensate participants who are harmed in a trial. For this reason, evidence of appropriate insurance and indemnity arrangements must be provided as part of documentation submitted for ethics review.

Do public hospitals provide insurance for their employees?

All public hospitals provide insurance to cover employees, including clinical trial researchers directly engaged by the institution. In some situations, such as where the researcher is a visiting medical officer or adjunct appointee, and therefore not an

employee of the institution, the individual may also need to take out their own professional indemnity insurance. This insurance is often a standard requirement of registration for health practitioners.

Do private health providers provide insurance for their employees?

While an employee engaged by a private health provider is normally covered by the institution's insurance, researchers such as medical practitioners are not usually employed directly by a private provider. Instead they have an arrangement which enables them to practise privately.

Researchers with such an arrangement are generally required to have in place professional (also known as medical) indemnity insurance that includes coverage for clinical trials as a condition of conducting a clinical trial. The researcher must provide evidence to the private hospital that they have insurance in place before the trial commences.

Who provides insurance and indemnity cover for clinical trials?

In the public sector

In the public sector, each State and Territory provides indemnity or insurance coverage in relation to their clinical trial activities. The arrangements are implemented and managed through a State or Territory agency and may take the form of insurance or an indemnity fund or a self-insurance scheme. A summary table of State and Territory insurance arrangements can be found at the end of the FAQs.

Clinical trials coverage is usually a subset of the medical indemnity or professional indemnity coverage. Details for each State and Territory scheme can be found at:

ACT - Australian Capital Territory Insurance Authority

NSW- Treasury Managed Fund

NT- A self-insurance program that covers the risk of the Territory's agencies

QLD - Queensland Government Insurance Fund

SA - SAICORP

TAS - Tasmanian Risk Management Fund

VIC - Victorian Managed Insurance Authority

WA - RiskCover

In the university sector

The university sector has access to the Unimutual scheme, which covers trials conducted by university researchers. Unimutual is a discretionary mutual, operating on not-for-profit principles and was formed to offer higher education and research institutions a cost-effective alternative to insurance.

In the private sector

In the private sector, sites that conduct clinical trials will usually purchase clinical trials insurance from a commercial insurer.

Commercial insurers offer the following types of insurance policies in each of these categories:

- A comprehensive insurance policy covering all clinical trials conducted by an insured during a specified period; or
- An insurance policy that is specific to, or covers only, a particular clinical trial. This type of policy is purchased on a trial by trial basis.

Does the clinical trial site require insurance and indemnity cover (or is this already covered by the trial sponsor for commercial trials)?

Yes. A trial site requires either its own insurance cover or an indemnity from a sponsor to cover the trial site's liabilities. In general, the commercial sponsor's insurance or indemnity arrangements do **not** provide cover for the trial site's liabilities and so a separate insurance policy or indemnity is required.

What indemnity and insurance requirements do States and Territories impose on commercial sponsors of clinical trials?

Public sector institutions conducting a clinical trial require the sponsor to provide a contractual indemnity to the trial site and evidence of insurance arrangements.

Schedule 2 in the report details each State and Territory's specific minimum requirements for sponsors. The ethical principles relating to insurance requirements are also set out in sections 3.3.24-3.3.25 of the National Statement.

What indemnity and insurance requirements do States and Territories impose on non-commercially sponsored trials?

Schedule 2 of the report details each State and Territory's specific minimum requirements. These include ensuring that external not-for-profit sponsors, e.g. a charity or network, have sufficient indemnity and insurance arrangements.

TRIAL TYPE

Does the phase of trial affect the insurance and/or indemnity cover?

At the time of the report, indemnity and insurance providers did not distinguish between the types or phases of clinical trials with respect to providing coverage.

Do State and Territory indemnity and insurance arrangements distinguish between single centre and multi-centre trials?

The State and Territory indemnity and insurance arrangements cover both single centre and multi-centre trials. Each State and Territory has its own insurance and

indemnity arrangements which cover trials at public health trial sites in their jurisdiction.

HUMAN RESEARCH ETHICS COMMITTEES (HREC)

Does the insurer/indemnity provider have explicit requirements or prohibitions regarding acceptance of a HREC review that is performed by a HREC of another body, whether in the public sector or private sector?

The report did not identify any specific issues regarding the indemnity or insurance arrangements for clinical trials that would prevent a public health service from accepting ethical review performed by an external, private sector HREC.

However, a number of State and Territory health departments have formal policies or procedures, and some have developed practices, that may prevent a public health service under their jurisdiction from accepting ethical review performed by a HREC outside that jurisdiction, whether in the private or public sector.

This issue should be less prevalent for institutions participating in the National Approach to Single Ethical Review, or in the National Mutual Acceptance (NMA) system, and for Phase II, III and IV clinical trials.

If in doubt, you should check with the institution's research office.

What about insurance and indemnity provisions in relation to the establishment of a national approach for research governance

The report concluded that indemnity and insurance arrangements should not be a barrier to a national good practice process for research governance or, in the public sector, with the National Mutual Acceptance (NMA) system using existing indemnity and insurance arrangements of the States and Territories.

Are HREC members covered by any insurance and indemnity arrangements?

Members of a public health service's HREC are either specifically identified as being entitled to indemnity (for example, the arrangement states that 'members of a HREC' are covered) or fall within a group (for example, 'members of any committee appointed by the Agency') entitled to indemnity.

However, in certain situations, indemnity may only be extended to employees of the public health service (see schedule 1 of the report for details for each State and Territory).

The expectation and practice of public health services is that **all** members of their HRECs are covered by the public health service's indemnity and insurance arrangements.

TRIAL PARTICIPANTS

Are trial participants directly covered by the health service's insurance and indemnity arrangements?

No. A participant in a clinical trial (or, indeed, any patient of a public health service) is not an insured or indemnified person under any of the State or Territory indemnity and insurance arrangements. If injured, a trial participant would be required to make and prove their claim against the relevant public health service.

Table 1: Summary of who is covered by which indemnity and insurance policies.

	Sponsor	Trial site	HREC members	Researcher/Investigator: Public hospital	Investigator: private hospital	Participant
Covered by the commercial sponsor's indemnity policy	**Yes**	**No**	**No**	**No**	**No**	**No**
Insured by site's insurance	**No**	**Yes**	**No**	**Yes**	**Depends on policy**	**No**
State and Territory's indemnity cover: site	**No**	**Yes**	**Usually**	**Yes**	**N/A**	**No**
Personal (professional medical) indemnity cover- private sector	**No**	**No**	**No**	**No**	**Yes**	**No**