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Indemnity and Insurance Arrangements for Clinical Trials in the Public and Private Sectors in Australia

May 2014

Indemnity and Insurance Arrangements for Clinical Trials in the Public and Private Sectors in Australia

**Report to the National Health and Medical Research
Council**

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Definition of terms used in this report

CRG means collaborative research group or cooperative research group.

CRO means contract research organisation.

CTRA means clinical trial research agreement.

First Report means the report '*Report on current indemnity and insurance practices within multi-centre health and medical research*' commissioned by the NHMRC during the development of the HoMER project and prepared by DLA Phillips Fox.

GCP Guideline means the Committee for Proprietary Medicinal Products (CPMP)/International Conference on Harmonisation (ICH) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted with annotation by the TGA.

HREC means Human Research Ethics Committee.

Indemnity means a legally binding promise by which one party undertakes to accept the risk of loss or damage another party may suffer and/or to compensate the other party for the loss or damage.

Insurance means a form of indemnity provided by an insurer under which the insurer agrees to indemnify the party purchasing the insurance policy in respect of certain specified losses and liabilities upon the occurrence of certain specified events. Types of insurance that are relevant for the conduct of clinical trials include: professional indemnity, medical indemnity, public liability and products liability.

MAI Ethics means the Medicines Australia Form of Indemnity for Clinical Trials (HREC Review Only). Where the context requires, this includes the MTAA Indemnity Form for HREC review only.

MAI Standard means the Medicines Australia Form of Indemnity for Clinical Trials (Standard). Where the context requires, this includes the MTAA Standard Indemnity Form for a Clinical Investigation.

MRI means medical research institute.

MTAA means the Medical Technology Association of Australia.

National Statement means the National Statement on Ethical Conduct in Human Research (2007) published by the NHMRC.

NHMRC means the National Health and Medical Research Council.

NMA means the National Mutual Acceptance arrangement for scientific and ethical review of multi-centre clinical trials undertaken in public health organisations developed and implemented by the States and Territories, which from 1 November 2013 involved the following participants: New South Wales, Queensland, South Australia and Victoria.

Professional indemnity insurance means a type of insurance that protects a professional service provider against claims for negligence and breach of duty.

Public health service means a health service funded and operated by the Commonwealth Government or by a State or Territory Government.

Public liability insurance means a type of insurance that protects an insured against claims resulting from accidents or injuries that occur as a result of the insured's business activities and against claims resulting from accidental damage to property owned by someone else.

SIR means self-insured retention.

SOP means standard operating procedure.

TGA means the Australian Therapeutic Goods Administration.

1 Executive Summary

There are two separate, though related aspects to indemnity and insurance arrangements for clinical trials in the public and private sectors. The first concerns the indemnity and insurance arrangements taken out (either on its own or on its behalf) by an entity that conducts or participates in the conduct of a clinical trial to protect that entity against liabilities that may arise in relation to a clinical trial. The second concerns the indemnity and insurance requirements imposed by an entity that conducts a clinical trial on another entity that is involved in the conduct of that trial.

In the public sector, each State and Territory jurisdiction provides indemnity or insurance coverage to its respective public health services 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, an indemnity fund or a self-insurance scheme. Clinical trials coverage is usually a subset of the medical indemnity or professional indemnity coverage which is provided by that agency to public health services in the relevant jurisdiction.

The State or Territory agency that provides indemnity or insurance cover may have specific requirements or guidelines regarding the conduct of a clinical trial by a public health service. However, more commonly, such requirements or guidelines are established by the respective State or Territory health department. These requirements typically concern indemnity and insurance obligations that a public health service should impose on another party involved in the clinical trial, such as a commercial sponsor.

In the private sector, entities that conduct clinical trials will usually purchase clinical trials insurance from a commercial insurer. The university sector also has access to the Unimutual scheme. Insurance policies written by commercial insurers for clinical trials generally contain the usual terms and conditions that are found in professional indemnity and medical indemnity policies. Any policy or practice concerning indemnity or insurance arrangements for clinical trials is generally developed internally by a private health service.

This review has not identified any specific issue 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/Territory health departments have formal policies or procedures, and some have developed practices, that prevent a public health service under their jurisdiction from accepting ethical review performed by any HREC outside that jurisdiction, whether in the private or public sector.

Nevertheless, the States and Territories have demonstrated through their participation in NMA that they are prepared to make exceptions to such a policy or practice where required. The NMA system utilises the existing indemnity and insurance arrangements of the States and Territories and may provide the basis of a model for a national approach which includes the private sector.

Key themes and issues

- ▶ Public sector entities are affected by any requirement or policy of their respective health department and/or their respective State/Territory indemnity or insurance provider that concerns indemnity and insurance arrangements for their clinical trial activities and whether they can accept ethical review performed by an external HREC.
- ▶ Private sector entities are affected by any requirement imposed by their (commercial) insurer regarding their clinical trial activities. Further, private sector entities may have developed their own requirements regarding indemnity and insurance arrangements for clinical trials and whether they will accept ethical review performed by an external HREC.

- ▶ As a general rule, from the perspective of providing coverage, the indemnity and insurance arrangements in the public and private sectors treat clinical trials uniformly; in other words, it is uncommon for the indemnity and insurance arrangements to distinguish between clinical trials on the basis of the phase of the trial.
- ▶ In both the public and private sectors, certain indemnity and insurance requirements are imposed upon third parties that participate in the conduct of a clinical trial for certain categories of clinical trials. The most typical example is the imposition of specific indemnity and insurance requirements on commercial sponsors of clinical trials.
- ▶ The indemnity and insurance arrangements of public sector entities generally extend coverage to clinical trial researchers who are employees of that entity and to the HREC of that entity.
- ▶ In the private sector, clinical trial researchers who are employees of the relevant private sector entity may be covered under the entity's clinical trials insurance arrangements. However, many clinicians conducting clinical trials in a private sector entity will not be employees of that entity. Researchers that are not employees are required to have in place professional indemnity or medical indemnity insurance that includes coverage for clinical trials as a condition to participate in the conduct of a clinical trial.
- ▶ There are certain misconceptions amongst researchers and staff (including staff in ethics or research offices) of health services around indemnity and insurance arrangements for clinical trials. Two of the more notable misconceptions are the following:
 - That a research subject in a clinical trial is 'covered' or 'insured' by the indemnity and insurance arrangements of the health service.
 - That a health service's insurance or indemnity arrangements only cover CRG or investigator initiated clinical trials and not commercially sponsored clinical trials because 'the sponsor's insurance covers commercially sponsored studies'.
- ▶ The development of NMA demonstrates that the States and Territories have the capacity to overcome or resolve any jurisdictional impediments (whether real or perceived) to the operation of a national system of ethical review of clinical trials, at least to the extent that such system operates within the public sector.
- ▶ NMA gives only limited rights to private sector entities to participate in that system. Unlike NMA, a comprehensive national approach must extend the same participation rights to the private sector. If private sector participants can demonstrate they meet the requisite ethical and governance standards, there can be no sustainable basis to deny them such participation rights.
- ▶ Many stakeholders, including commercial sponsors and commercial insurers, are supportive of and would welcome processes that standardise indemnity and insurance requirements across the public and private sectors.

2 Background to this review

The purpose of this review

NHMRC is exploring measures to improve the competitiveness of Australia's clinical trial research sector as part of ongoing work under the *Expediting Clinical Trials Reforms* initiative. A proposed initiative includes streamlining ethical and governance review of clinical trials. An important element of this approach is identifying, and where necessary, resolving any legal and policy barriers to the review, approval and conduct of clinical trials.

NHMRC engaged Rallis Legal to review and report upon the indemnity and insurance arrangements for clinical trials existing in and used across the public sector and the private sector. The review has also attempted to identify any barriers arising from or relating to the indemnity and insurance arrangements that may have an impact on the adoption of a nationally consistent process for the review and approval of clinical trials.

The objectives of this review are to outline the current indemnity and insurance arrangements concerning clinical trials across the public and private sectors, to identify any potential barriers concerning those arrangements to a national approach for ethical and research governance and to provide recommendations, where relevant, regarding how any identified issues may be resolved.

Essentially, this review has considered the following issues:

- ▶ The nature and features of the current indemnity and insurance arrangements for clinical trials across the States and Territories.
- ▶ The nature and features of the current indemnity and insurance arrangements for clinical trials across the private sector.
- ▶ Whether there are any legal, policy or operational issues concerning clinical trials indemnity and insurance arrangements that might act as a barrier to a streamlined approach to ethical and governance review of clinical trials.

The process for this review

This review considers and incorporates, where appropriate:

- ▶ The review of the First Report.
- ▶ The review of relevant material regarding indemnity and insurance arrangements in the public sector and the private sectors.
- ▶ Consultation with a selective group of stakeholders¹ identified by the NHMRC, as well as other relevant stakeholders.
- ▶ The preparation of this report and its findings.

The requirement for indemnity and insurance in clinical trials

There are essentially two aspects regarding indemnity and insurance from the perspective of an entity that conducts clinical trials:

- ▶ First, the indemnity and insurance arrangements that the entity has or puts in place to protect it against liabilities that it may incur or suffer in the course of its clinical trial

¹ In this report, the term 'stakeholder(s)' specifically refers to these people.

activities. Where these take the form of insurance, the 'insured' will typically be the entity, its directors and officers and its employees. The considerations in this respect are not unique to clinical trials – such an entity will have various types of liability insurance in place to protect it against liabilities incurred in relation to its other activities.

- ▶ Second, the indemnity and insurance requirements imposed by a party conducting a clinical trial upon another party that is involved in that clinical trial in some capacity – for example, as a sponsor, collaborator or contributor. The most common requirements are for the other party to provide a (contractual) indemnity to the first party and evidence of its insurance arrangements. The effect of such requirements is twofold:
 - the indemnity given by the other party protects the first party against certain liabilities; and
 - as the other party will have insurance covering its activities, the first party will be reasonably assured that the other party should be able to meet a liability that arises from its (negligent) conduct. (Indeed, if there is a requirement for the first party to be included as an insured on the other party's insurance arrangements, then the first party will have a direct right to seek protection against the insurer.)

An obvious motivation for an entity that participates in the conduct of clinical trials to implement appropriate indemnity and insurance arrangements is to protect itself and its employees against liability claims. Such protections seek to preserve its financial and operational interests. However, there are also ethical and regulatory reasons for an entity to put in place such arrangements. These include:

- ▶ The ethical principles set out in the National Statement. The relevant sections read:
 - 3.3.24 Institutions must be satisfied that sponsors of trials have made the indemnity or insurance and compensation arrangements required by CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices and the TGA.
 - 3.3.25 In addition to the requirements in paragraph 3.3.24, institutions must also have arrangements to compensate participants for harm resulting from negligence in research to which this chapter applies.
- ▶ The requirements of the TGA. The TGA advises that the responsibilities of a sponsor (that is, the individual who endorses the CTN or CTX form) of a clinical trial includes:
 - Provision of appropriate insurance and indemnity for the trial and trial-related staff, as well as measures for subject compensation for trial-related injury.²

The agreements and arrangements that entities conducting clinical trials enter into may be a further source of obligations and requirements regarding indemnity and insurance. A prominent example is the widespread acceptance and use of the Medicines Australia CTRA for commercially sponsored clinical trials and the MAI Standard and MAI Ethics which require commercial sponsors to provide indemnities to entities conducting a clinical trial. These indemnities are supported by a requirement for certain types and levels of insurance.

² *The Australian Clinical Trial Handbook* (March 2006) published by the TGA, page 26.

3 Current indemnity and insurance arrangements in the States and Territories for public sector clinical trials

This review has identified that the indemnity and insurance arrangements concerning the conduct of clinical trials in the public health sector of the States and Territories remain broadly the same as those reported in the First Report.

There are essentially two elements to the indemnity and insurance arrangements and requirements in the States and Territories in relation to the conduct of clinical trial. The first element is the indemnity and insurance arrangements organised by State or Territory Governments or government agencies which provide indemnity or insurance cover to State and Territory public health services in relation to their clinical trial activities. The second element is the indemnity and insurance requirements imposed by State or Territory Governments (or Government departments) or the agencies that provide indemnity or insurance on third parties that participate in the conduct of trials with their respective public health services.

3.1 Indemnity and insurance provided by State or Territory insurers or agencies

The existing indemnity and insurance arrangements organised by State and Territory insurers or agencies are set out in Schedule 1. The indemnity and insurance arrangements provide protection to State and Territory public health services (and other eligible entities) against liabilities they may incur in connection with their activities, including in connection with the conduct of clinical trials.

The relevant, salient features of these arrangements are the following:

- ▶ The indemnity or insurance cover of public sector clinical trials is provided by an insurer or indemnity provider or indemnity fund that is usually established pursuant to a statute for that jurisdiction.
- ▶ If cover is provided by way of insurance, it generally has the customary features of insurance cover - the insurance is recorded in a policy or policies of insurance, the policy contains the usual terms and conditions for insurance, it covers the types of liabilities ordinarily covered by insurance policies and the insured must pay a premium for the cover.
- ▶ 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.
- ▶ The indemnity or insurance arrangements in each State and Territory treat clinical trials as a class of activity undertaken by public health services.
- ▶ Cover for clinical trial activities usually falls within the categories of professional liability or medical liability coverage under the relevant insurance policy or indemnity arrangements.
- ▶ The indemnity and insurance providers do not distinguish between the types or categories of clinical trials with respect to providing coverage. In other words, a public health service will be insured or indemnified against any liability that it incurs in the course of conducting any clinical trial that is part of its ordinary activities, regardless of whether the clinical trial is

commercially sponsored, a CRG study or an investigator initiated study. Even if the public health service has obtained an indemnity from another party for certain clinical trials (for example, from a commercial sponsor of a commercially sponsored clinical trial), or the public health service is named as an insured on another party's insurance policy, this does not alter the public health service's entitlement to indemnity or insurance cover from its respective State or Territory insurance or indemnity provider.

- ▶ The existing State and Territory indemnity and insurance arrangements do not distinguish between single centre or multi-centre clinical trials. This may reflect a view of indemnity and insurance providers that there is no practical difference between them; or perhaps indemnity and insurance providers lack a sufficient understanding of clinical trials and any risks inherent in their conduct to discern any difference.
- ▶ There does not appear to be any specific exclusion in any of the State or Territory indemnity or insurance arrangements concerning particular aspects of the conduct of a clinical trial.

For example, there does not appear to be any specific exclusion regarding a public health service's acceptance of the ethical review of an HREC external to that public health service. The stakeholders that were consulted could not identify any such exclusion. While the author did not review all of the terms and conditions of the indemnity and insurance arrangements in each State and Territory (because they were either not available or would not be provided for commercial in confidence reasons), it would be surprising if such a specific exclusion exists.

- ▶ The definition of an 'insured' or person covered under the indemnity and insurance arrangements extends beyond the public health service itself. The arrangements generally also cover directors, officeholders, employees, committee members and even volunteers for activities performed in the course of their employment or appointment.
- ▶ In at least one jurisdiction there is a requirement for a proposed clinical trial to be submitted to the insurer/indemnity provider for a risk assessment as part of the approval process. However, there is no requirement in any jurisdiction to notify the insurer of the completion of a clinical trial.
- ▶ Members of a public health service's HREC are either specifically identified as being entitled to indemnity (for example, the arrangement stated that 'members of a HREC' are covered) or appeared to fall within a group (for example, 'members of any committee appointed by the Agency') entitled to indemnity. However, certain arrangements stated that they extended indemnity only to employees of the public health service; others were silent on this issue, creating uncertainty as to whether HREC members that were not employees of a public health service would be covered. In either case, the expectation and practice of public health services is that members of their HRECs are covered by the public health service's indemnity and insurance arrangements. The stakeholders that were consulted generally indicated that they operated on the basis that members of their HREC were covered by their organisation's indemnity and insurance arrangements.
- ▶ A number of State and Territory arrangements do not provide indemnity or insurance cover to private practitioners or researchers who are not employed by the relevant public health service. In some cases, where they do provide cover, the private practitioner or researcher must meet certain conditions to be entitled to that cover.

- ▶ The indemnity and insurance cover provided under the State and Territory arrangements is (negligence) liability coverage. The State and Territory indemnity and insurance providers do not provide no fault cover.
- ▶ Often there is a misconception amongst researchers and staff (including staff in ethics or research offices) of public health services that a research subject in a clinical trial is 'covered' or 'insured' by the indemnity and insurance arrangements of that public health service. A research subject or participant of a clinical trial (or 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. In order to be compensated for any personal injury or loss they might suffer as a result of participating in a clinical trial, a participant would be required to make and prove their claim against the relevant public health service. In that case, the indemnity or insurance provider which is at risk for that claim would indemnify the public health service for any loss it incurs in relation to that claim.
- ▶ Another misconception encountered during the course of this review amongst such staff is that the State or Territory insurance or indemnity arrangements only cover CRG or investigator initiated clinical trials and not commercially sponsored clinical trials because 'the sponsor's insurance covers commercially sponsored studies'. As noted above, the State and Territory insurance or indemnity arrangements provide coverage to their insured or indemnified entities in relation to all types of clinical trials. If a claim is made against a public health service, it would be expected that the public health service will usually first turn to its respective insurance or indemnity provider to provide indemnity to it in relation to the claim. The State or Territory insurer or indemnity provider may then pursue a commercial sponsor (or any other party) which has caused or contributed to the claim. In those circumstances, the indemnity provided by such party to the public health service and the other party's insurance arrangements are likely to be relevant to the State or Territory insurance or indemnity provider's ability to recover its loss.

3.2 State and Territory indemnity and insurance requirements for other parties participating in the conduct of a clinical trial

General

The requirements imposed in each State and Territory upon parties involved in the conduct of a clinical trial at a public health service are set out in Schedule 2.

Generally, a public health service must ensure that an entity which is involved in some capacity in the conduct of a clinical trial at that health service - for example, as sponsor or collaborator - must comply with the applicable State or Territory requirements for that class of clinical trial.

The relevant, salient features of these requirements are the following:

- ▶ In broad terms, there are two elements:
 - A requirement for the other entity to provide some form of indemnity to the public health service which is permitting the conduct of the clinical trial on its patients.
 - A requirement for the other entity to provide evidence that it has in place certain types and levels of liability insurance that meet prescribed, minimum requirements.
- ▶ The indemnity and insurance requirements imposed upon parties that are involved in the conduct of a clinical trial of a public health service have gradually become more standardised. This is particularly the case with a number of States, notably New South

Wales, Victoria, Queensland and Western Australia, which now have relatively similar requirements compared to what was the case eight or ten years ago.

- ▶ The requirements may be prescribed by the relevant State or Territory insurance or indemnity provider - for example, in Victoria, the statutory State insurer, the Victorian Managed Insurance Authority establishes the relevant requirements - or by the relevant State or Territory Government Department – for example, in New South Wales, Queensland and Western Australia.
- ▶ The requirements are established in various ways, such as written guidelines, policy directives, departmental policy or SOPs.
- ▶ The status of the requirements in each State and Territory - in relation to whether compliance is mandatory and the consequences of non-compliance - is variable. The requirements may be established or expressed as guidelines, with which compliance is (strongly) recommended but may not be mandatory³, or they may be established or expressed as directives, policies or directions with which compliance is mandatory.⁴
- ▶ There remain a number of States and Territories that do not have explicit, prescribed requirements set out in a specific document. The arrangements in these States are informal and less structured. For example, in South Australia, the insurance arrangements for commercially sponsored clinical trials conducted in the public health sector must be submitted to the Manager, Insurance Services, Finance and Administration in the Department of Health for approval; the Manager assesses the arrangements against certain minimum requirements developed by that office but those requirements are not published.
- ▶ The implementation and use of standard or template documents has assisted the standardisation process across the States and Territories. These documents include:
 - the MAI Standard and the MAI Ethics;
 - the standard CTAs for commercially sponsored, CRO and CRG clinical trials that have been developed in conjunction with Medicines Australia; and
 - the Clinical Investigation Research Agreement that has been developed in conjunction with the MTAA.

3.3 State and Territory Government requirements that may impact on streamlining of ethical and governance review of clinical trials

This section sets out policies, procedures and practices of the States and Territories identified during the course of this review which may present an impediment or may be relevant to a streamlined approach to ethical review and governance arrangements for clinical trials. In most cases, the policies, procedures and practices that have been identified do not directly concern indemnity insurance arrangements but may be relevant to a national approach.

Australian Capital Territory

The ACT Health research office reported that all current clinical trials being conducted in the ACT Health system have been reviewed by the ACT Health HREC. There is no policy, guideline or directive that provides that this should be the case or, alternatively, that review by an HREC that

³ VMIA *Clinical Trials – Insurance and Risk Management Guidelines* (Version 2, September 2012)

⁴ The various NSW Policy Directives regarding clinical trials state that compliance with them ‘is **mandatory** for NSW Health and is a condition of subsidy for public health organisations’.

is external to the ACT Health system should not be accepted by an ACT Health body - it appears that this simply reflects a practice that has developed.

The ACT has agreed to the principles of NMA but is not yet a signatory to the NMA process. ACT Health indicated that outside of the NMA, it has not considered its position on ACT Health bodies accepting review performed by an external HREC, including a private HREC.

Northern Territory

The current position in the Northern Territory is that all clinical trials being conducted in the Northern Territory public health system are reviewed by an HREC within that system. While there is no specific policy on this issue, there appears to be an informal understanding that a Northern Territory public health service would not accept review conducted by a HREC external to the Northern Territory public health system.

New South Wales

New South Wales is a signatory to and participates in NMA. A NSW public health organisation is permitted to accept the ethical review of an NHMRC certified HREC of a public health service in Victoria, Queensland or South Australia in accordance with the terms of NMA. NSW also has 'lead HRECs' with its public health system that can provide a single ethical review for multicentre studies taking place entirely within that health system.

With the exception of a clinical trial reviewed under NMA, NSW Health prevents a NSW public health organisation from accepting ethical review undertaken by a HREC that is located outside of the NSW public health system. NSW Health's position is enunciated as follows:

Each Public Health Organisation must accept ethical and scientific review undertaken by its local HREC or a lead HREC as sufficient review for the purposes of the project being conducted at site(s) under its control. This applies to both full and expedited HREC review.

- A local HREC is an HREC established by a Public Health Organisation to provide ethical and scientific review of human research to be conducted at sites under its control. Some Public Health Organisations support more than one local HREC.
- A lead HREC is a local HREC accredited by the Director-General of the Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research; and/or (b) general research.

The accreditation standards are available at:

http://www.health.nsw.gov.au/resources/ethics/research/Third_round_Accreditation_Standards_and_Guidance_Apr_10_pdf.asp

Where the human research project involves the conduct of research at sites under the jurisdiction of more than one local HREC, the project must be reviewed by a lead HREC.⁵

NSW Health indicated that it is currently reviewing its position regarding whether a NSW Health public health organisation would be permitted to accept ethical review by an HREC of a private health service.

Queensland

Queensland is a signatory to and participates in NMA. A Queensland Health public health organisation is permitted to accept the ethical review of an NHMRC certified HREC of a public

⁵ NSW Health Policy Directive: *Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations* (8 September 2010), page 3.

health service in Victoria, New South Wales or South Australia in accordance with the terms of NMA.

The policy position of Queensland Health is that for multicentre studies taking place in Queensland public health organisations (other than those under NMA), a Queensland Health public health organisation HREC must review that study.⁶

South Australia

South Australia is a signatory to and participates in NMA. An SA Health public health service is permitted to accept the ethical review of an NHMRC certified HREC of a public health service in Victoria, New South Wales or Queensland in accordance with the terms of NMA.

On the question of review by a HREC outside the jurisdiction of SA Health, a Research Ethics Operational Policy Directive of SA Health provides:

Projects that have been reviewed by a HREC outside the jurisdiction of SA Health *may* be reviewed again at the discretion of a SA Health HREC. However, if the research is being undertaken at multiple SA Health sites, these projects should only be reviewed once by an additional SA Health HREC to minimise further duplication of review.⁷ (emphasis added)

The author suggests that there is some ambiguity in this policy statement on the issue of whether a public health service could accept the review of an HREC outside of the SA Health system. In any case, SA Health indicated that a public hospital in South Australia is not permitted to accept the ethical review performed by a HREC outside the South Australian public health system, except for HREC review performed under NMA. It was suggested by an SA Health representative that it is also the position of SA Health's insurer that a public hospital in South Australia is not permitted to accept the ethical review performed by a HREC outside the South Australian public health system, although no specific insurance exclusion in this regard was identified. Further, SA Health indicated that it perceives that accepting ethical review conducted by a private entity's HREC carries greater risk than accepting the review of a public health service HREC.

Tasmania

The Tasmanian Department of Health and Human Services (**DHHS**) indicated that it does not have any formal policy or requirements regarding indemnity and insurance for clinical trials. Further, the details regarding the indemnity and insurance requirements imposed on third parties involved in the conduct of clinical trials set out in Schedule 2 reflect custom and practice, rather than any prescribed set of guidelines or policy.

All clinical trials currently being conducted in the Tasmanian public health sector are ethically reviewed by the Tasmania Health and Medical HREC which operates by a joint agreement between the DHHS and the University of Tasmania.

There is no formal DHHS policy that prevents a public health service from accepting ethical review of a clinical trial performed by another HREC. Moreover, a senior DHHS representative indicated that he was not aware of any DHHS requirement that would act as an impediment to a Tasmanian public health organisation accepting the review of an external HREC. However, one Tasmanian public health organisation indicated that its internal '*Research and Clinical Drug Trials Policy*' requires that all clinical trials it performs must be approved by the Tasmania Health and Medical HREC. Further, that policy provides that even if a clinical trial has been approved

⁶ Queensland Health, *Research Management Policy Implementation Standard - Ethical and Scientific Review of Human Research*, 9 December 2010.

⁷ SA Health, *Research Ethics Operational Policy Directive*, 25 June 2013, page 6.

by another 'NHMRC certified HREC', it must still be submitted for approval to the Tasmania Health and Medical HREC.

Victoria

The Victorian Department of Health has no formal policy regarding the requirement for a public health service to only accept the HREC review of another Victorian public health service.

Victoria participates in NMA and will accept review conducted by an HREC that is external to the Victorian public health system under NMA.

Western Australia

WA Health refers to three systems of ethical review regarding multicentre studies conducted in Western Australia. The systems are the following:

- ▶ WA Health Single Ethical Review of Multi-Centre Research (WA Health Single Ethical Review)

All multi-centre research projects being conducted at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health must be ethically and scientifically reviewed only once, by a Lead WA Health HREC.

Presently, a WA public health service may only accept the review of another WA public health service HREC.

- ▶ National Mutual Acceptance of Ethical and Scientific Review for Multi-Centre Clinical Trials Conducted in Public Health Organisations (National Mutual Acceptance)

WA is not yet a signatory to NMA. WA Health states that it '*anticipates that it will be able to implement [the NMA] process in 2014, once all requirements are in place.*'⁸ It is unclear whether this means that WA intends to become a signatory to NMA in 2014.

- ▶ The NHMRC's National Approach to Single Ethical Review of Multi-centre Research (National Approach)

WA Health states that it envisages that once the National Mutual Acceptance process has been implemented and established within WA Health, the National Approach process will be introduced to extend single ethical review to include all human research. WA Health's position is that it would permit a public health service to accept review of a public or private sector external HREC, provided the HREC has been certified by the NHMRC.

Discussions with WA Health confirmed that it is the policy and practice in the Western Australian public hospital system that WA Health hospitals cannot currently accept the review by an HREC external to that system.

However, by way of a research governance policy and procedures document, WA Health imposes the following indemnity and insurance requirements regarding ethical review by a HREC outside the WA Health public health system:

In regards to a clinical trial which has been reviewed externally to WA Health by a private HREC the following indemnity requirements must be adhered to:

- commercial trial – where the private HREC review concerns a commercial trial, the two MA forms of indemnity would need to be provided by the sponsor (one to cover the private HREC

⁸ Government of Western Australia, Department of Health website:
<http://www.health.wa.gov.au/researchdevelopment/home/hrec.cfm>

and one to cover the WA Health institution for the conduct of the trial). Along with the HREC approval, the CPI would need to provide the RGOs with a copy of the HREC indemnity, so that the RGOs would have copies of both indemnities on file; and

- non-commercial trial - where the private HREC review concerns a non-commercial trial, the private HREC would need to provide evidence that it holds sufficient and appropriate insurance. In terms of WA Health's duty of care to participants, the institution should ensure that the HREC's insurance cover would respond to a claim, alleging negligence in the review, made by a participant against the HREC.⁹

This research governance policy and procedures document suggests that acceptance of review by an HREC external to the WA Health system is permitted. It is difficult to reconcile the statements in that document with WA Health's otherwise stated policy position on this issue. In any event, the practice within the WA Health public health system appears to be that external HREC review is currently not permitted.

Discussion of State and Territory issues relevant to a national approach to the approval and conduct of clinical trials

The States and Territories have developed their own processes and procedures in relation to ethical review and governance of clinical trials within their respective public health sectors. While differences exist between them, it is equally clear that the trend over the last decade has been for those processes and procedures to increasingly become more similar. The adoption and use of template documents such as the Medicines Australia CTRAs and the MAI Standard and MAI Ethics across the jurisdictions have contributed to this standardisation process. The NMA model provides an example of a model that seemingly overcomes any impediments (whether actual or perceived) to a standardised system that works across the jurisdictions.

While this review was not specifically tasked with considering whether there are any Constitutional or any State or Territory legislative impediments to a national approach to ethical review and research governance for clinical trials, none of the jurisdictions identified any such impediments. In fact, some jurisdictions indicated that they were not aware of any laws that would prevent their State or Territory from participating in a national approach. While this may require further investigation, it would appear that if any legislative impediment existed, then it would likely have prevented the implementation of the NMA system.

If there is any impediment to a national approach to ethical review and research governance, such impediment is likely to exist in a policy or guideline of a jurisdiction or the interpretation and application of that policy or guideline. The policies and guidelines concerning acceptance of ethical review performed by an external HREC provide a relevant illustration. In some cases, an impediment may merely be perceived to exist or has been created through custom or practice. Again, the development and acceptance of NMA conveniently demonstrates that the States and Territories can make exception to any provincial policy or guideline, practice or custom and even any perception, that may otherwise hinder its participation in a standardised approach.

The stakeholders who were consulted generally expressed two opposing viewpoints on the issue of whether a public health service could or should accept ethical review conducted by an HREC outside that State's or Territory's public health system.

One view is that a public health service should not accept such review. As described above, some States and Territories have this type of requirement enshrined in a policy, guideline or SOP. Even where such policy, guideline or SOP contains an ambiguity about whether ethical review conducted by an HREC external to that State or Territory's public health system is

⁹ WA Health, *Research Governance Policy and Procedures*, November 2012, page 30.

permitted, the ambiguity was often interpreted by the stakeholders that were consulted in the negative – in other words, that it is not permitted.

The rationale most often cited for this approach (and view) is that the relevant jurisdiction has little or no confidence that an external HREC will possess the requisite expertise, experience and competence to properly provide ethical review of a clinical trial. Consequently, this might result in an increased liability exposure which may adversely affect a public health service's indemnity and insurance position.

In particular, it is considered that HRECs affiliated with or attached to a private organisation - including private hospital and university HRECs - lack the necessary experience and expertise to review clinical trials. At least one stakeholder expressed the view that it was inconsequential whether the external HREC had been certified by the NHMRC – such HREC's reviews would still not have the same status or achieve a level of acceptance as a review of a local public health service HREC. For example, it was suggested that it would be unlikely that a university HREC could acquire the requisite experience and expertise to provide ethical review of a clinical trial because universities do not have and do not treat patients. One stakeholder even suggested that NHMRC 'would never certify a university HREC for clinical trials' because university HRECs simply lack the relevant expertise. Another view expressed was that it was not a matter for the States and Territories to resolve the issue of private sector involvement in clinical trials – this was for the NHMRC to achieve.

However, it was acknowledged by a number of stakeholders that certain private HRECs may have the requisite expertise and experience to review clinical trials. The examples given included HRECs of certain private health services and the HRECs of Bellberry Limited. Given that these types of HRECs are likely to have as much expertise or experience as a public health sector HREC, the arguments against accepting ethical review performed by them would appear to be unsustainable.

The arguments against accepting the ethical review of an HREC of another public service in another State or Territory jurisdiction on the basis that their respective HRECs lack the requisite expertise are less forceful and less compelling. Indeed, the States and Territories have agreed on a process that achieves mutual acceptance – the NMA - and the four current participants of the NMA system (New South Wales, Queensland, South Australia and Victoria) are already accepting ethical review of public health sector HRECs located outside of their respective States.

The opposing view is that accepting the ethical review of an HREC outside the public health system is an operational matter and each public health service should be free to make its own decision on this issue. This view is reinforced by the fact that there is no specific exclusion in any of the indemnity or insurance arrangements to coverage if a public health service accepts the ethical review of an external HREC. Public health services currently enter into a variety of agreements and arrangements under which they rely on external (public and private sector) parties perform certain obligations. The performance of HREC review by an external party would be an example of such an arrangement and the risks and concerns could be addressed through appropriate governance and contractual arrangements – for example, by ensuring the party that provides HREC review has appropriate indemnity insurance arrangements in place to protect it and the accepting party.

A number of the jurisdictions who had a policy (formal or otherwise) against accepting external HREC review suggested that they would permit this to occur under a formal, structured system or arrangement. NMA provides an example of such a system – at least two jurisdictions who are currently participating in NMA have formal policies that otherwise prohibit their public health services from accepting external HREC review.

It was suggested that an alternative to a comprehensive system such as NMA is for a jurisdiction or even an individual public health service to enter into a contractual arrangement with a private entity that permits for HREC reviews to be shared generally or for a specific clinical trial or class of clinical trials. The contractual arrangement could also deal with other relevant issues, including research monitoring by the HREC, the investigation of research misconduct and access to clinical trials records.

3.4 National Mutual Acceptance

Since the First Report was published, the States and Territories have developed, and a number of them have implemented, the NMA system.

NMA is intended to be a national system for mutual acceptance of scientific and ethical review for multi-centre clinical trials conducted in publicly funded health services. It supersedes the interstate mutual acceptance initiative that was in place for the eastern seaboard States (New South Wales, Queensland and Victoria).

All of the State and Territory health departments have supported NMA. The introduction of the NMA system is phased. From 1 November 2013 New South Wales, Queensland, South Australia and Victoria commenced participation in the NMA system. It is anticipated that other States and Territories will eventually participate.

Under NMA, a multi-centre clinical trial being submitted for scientific and ethical review after 1 November 2013 and taking place in one or more of the participating States will be eligible for single ethical review. A proposal for such a clinical trial will be scientifically and ethically reviewed once only by a public health organisation HREC that has been certified by the NHMRC in clinical trials. However, at the least one State (South Australia) excludes phase 0 (first time in humans) and phase 1 clinical trials from a single review process.

In order to commence a clinical trial under the NMA system, a public health organisation in a participating State or Territory must obtain the authorisation of its Chief Executive or their delegate before the research can commence. For such authorisation to be given, the following requirements must be met:

- ▶ The research project must have been reviewed and approved by a NHMRC certified HREC that is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*.
- ▶ The research project must have been assessed by the public health organisation through a process of site specific assessment (which is commonly considered part of research governance processes).

While public health services and private organisations may participate in clinical trials ethically reviewed under the NMA system, only HRECs of public health services may act as a reviewing HREC of a clinical trial; a private organisation taking part in a multi-centre clinical trial may only accept the review of a public health service's HREC. Of course, the NMA does not limit the ability of a private organisation to conduct its own ethical review of a clinical trial, or to act as the 'reviewing' HREC for a multi-centre study involving only other private organisations.

Furthermore, the NMA does not prevent public health services from independently choosing to accept the ethical review of a private organisation for any particular clinical trial, although such acceptance will obviously be determined on an institution-by-institution basis.

Indemnity and insurance arrangements under NMA

There is no specific scheme or arrangement under NMA regarding insurance or indemnity for clinical trials that are ethically reviewed and conducted under that system.

Under NMA, each State or Territory must ensure that its certified HRECs are indemnified for their decisions in reviewing multi-centre clinical trials. For commercially sponsored clinical trials, the sponsor is required to continue to provide indemnity to the certified HREC that reviews the clinical trial, as it does in relation to commercially sponsored non-NMA clinical trials. For non-commercially sponsored NMA clinical trials, the expectation is that the indemnity and insurance arrangements for such clinical trials would be governed by the same general principles that concern non-NMA non-commercially sponsored clinical trials.

The certified HRECs are existing HRECs that operate within or under the auspices of public health services in the relevant States. The expectation of NMA participants is that the respective HRECs are indemnified under the usual indemnity and insurance arrangements existing in each jurisdiction for the public health sector. There is no distinction made between indemnity and insurance arrangements for HRECs in relation to NMA clinical trials or non-NMA clinical trials.

The significance of NMA to a national approach

The First Report detailed the issues raised, as well as the concerns and uncertainties expressed, by the States and Territories in relation to indemnity and insurance arrangements for multi-centre clinical trials. Essentially, the States and Territories articulated reservations about whether their existing indemnity and insurance arrangements would cover them for multi-centre clinical trial activities (including in relation to providing and receiving HREC review for multi-centre studies) and whether their involvement in such a system would increase their liability exposure.

In relation to a national system or approach (in the context of multi-centre studies), the First Report posited a number of models for indemnity and insurance. The States and Territories appear to have adopted a model for indemnity and insurance that concords with the principles of the model set out in option B of section 5 of the First Report. In doing so, each State and Territory is effectively pronouncing that it has sufficient confidence that its existing indemnity and insurance arrangements provide adequate cover to it in respect of its activities in connection with NMA. Moreover, each State and Territory is also pronouncing that it has similar confidence in the indemnity and insurance arrangements of the other States and Territories.

The author suggests it is therefore reasonable to conclude from the approach to indemnity and insurance under NMA that there should be few if any issues or obstacles concerning indemnity and insurance to the establishment of a national approach to the extent it relates to clinical trial activities between public health services, regardless of the jurisdiction in which they reside. The States and Territories have developed and agreed upon a solution which appears workable.

Of course, unfortunately, this model leaves out the private sector. It would appear that the States and Territories are ready to include each other in this type of system, given they share broadly similar structures and objectives. It is understandable that the States and Territories might be reluctant to adopt a similar approach to private sector bodies that wish to participate fully in NMA (as an institution accepting the ethical review outcome of another institution and/or reviewing HREC/institution), given the diversity of the nature and objectives of possible private sector participants. However, the conduct of clinical trials often involves the intersection of the public and private sectors at many levels and the sectors have historically found ways to collaborate and cooperate, notwithstanding their differences.

4 Current indemnity and insurance arrangements for clinical trials in the private sector

The private sector bodies that conduct clinical trials in Australia are diverse – they include for profit private hospital groups and independent private hospitals, not for profit private health groups and independent private hospitals, research institutes, universities, residential and aged care facilities, clinics and other private facilities.

This section begins by outlining the types of insurance that are available and typically purchased by private sector entities that conduct clinical trials. While there are a number of insurers offering these products in the Australian market, not unexpectedly, the features of the insurance products are relatively similar.

4.1 Clinical trials insurance in the private health sector

Types of clinical trials insurance provided by commercial insurers

The insurance products that are available in relation to clinical trials fall into two broad categories: liability insurance and no fault insurance. These are described further in the sections that follow.

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

- ▶ A blanket insurance policy covering all clinical trials conducted by an insured during a specified period; the period is often one year.
- ▶ 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.

1 General liability insurance

General liability insurance covers an insured's legal liability when they are found to be legally responsible for damage or loss suffered by a third party. General liability insurance includes public liability, product liability, professional indemnity and medical indemnity insurance.

In the context of clinical trials, general liability insurance will protect the insured against claims made by research participants for personal injury caused by a negligent act or omission of the insured.

2 No fault insurance

No fault insurance is a type of insurance where the entitlement to compensation is not linked to the ability to prove that a person's injuries were due to the fault of another. A no fault insurance policy responds to a claim for compensation, regardless of whether it can be proven that there has been any fault or negligence by either party. Typically, the terms of such insurance policy will set out conditions under which compensation will be payable.

Insurance in the private sector

The type of insurance that a private sector entity involved in clinical trials is likely to require and have in place will depend on the nature of its involvement in a clinical trial. A private hospital, research institute, clinic or individual researcher that conducts a clinical trial will at least require general liability insurance for professional indemnity and/or medical indemnity coverage. An entity that produces a study drug use in a clinical trial may also require products liability cover. Of course, it is not unusual for private entities to have in place a combination of different types of liability insurance that cover their clinical trial related activities.

Having in place an appropriate level of liability insurance that covers clinical trials is seen as an essential risk management measure. It is extremely unlikely that any private hospital, research institute, clinic or individual researcher would undertake a clinical trial and knowingly or deliberately fail to take out such insurance; this would also be extremely imprudent. Having said that, caution should be taken before assuming that any private entity's insurance policies cover clinical trials or that those policies provide a sufficient level of cover (that is, the total and occurrence claim limits are sufficient to cover the cost of any insurable event).

A private hospital, research institute, clinic or individual researcher may also have a requirement to take out no fault liability insurance. Such a requirement may arise internally – for example, to ensure that research participants are compensated regardless of fault – or externally – for example, if it is requirement of another collaborator in the clinical trial.

A commercial sponsor of a clinical trial (whether that clinical trial is conducted in the public or private sectors) will also require general liability insurance. As noted elsewhere in this report, the requirement for a commercial sponsor to have such insurance in place is a requirement of the States and Territories and many private sector organisations that conduct clinical trials.

A commercial sponsor of a clinical trial will also generally have in place no fault insurance. The need to have in place such insurance arises from the requirement for the sponsor to provide an MAI Standard or an MAI HREC in favour of an institution conducting the relevant clinical trial. Under the MAI Standard and the MAI HREC, a commercial sponsor is required to compensate research participants that are injured as a result of their participation in the clinical trial in accordance with the '*Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial.*' Those Guidelines provide that '*Notwithstanding the absence of legal commitment, the Sponsor should pay compensation to participants in clinical trials ("Subjects") suffering personal injury (including death) in accordance with these Guidelines.*'¹⁰ This indemnity and insurance requirement is now well established in Australia and accepted by commercial sponsors of clinical trials.

Features of clinical trials insurance provided by commercial insurers

Even though there are a number of different commercial insurers that provide clinical trials insurance, most of the products share similar features. While the specific details of the various insurers' policies and processes vary between them, these are some common features:

- ▶ The clinical trials insurance offered by commercial insurers does not usually make any coverage distinction on the basis of the type of clinical trial being performed or the parties who may be involved in the conduct of a clinical trial. In other words, a policy will ordinarily provide coverage to an insured for commercially sponsored, CRG or investigator initiated clinical trials that it might conduct.
- ▶ Some policies require an insured to notify the insurer of the details of each proposed clinical trial. The notification will usually involve the submission of documents regarding that clinical trial – for example, the protocol and the participant information sheet and consent form(s). Generally, the purpose of this process is to notify the insurer of the relevant details of the clinical trial, rather than to seek the insurer's approval for the conduct of the clinical trial. The insurer will then confirm or note that the relevant policy covers the submitted clinical trial. However, the insurer may exercise discretion to deny coverage if it considers the clinical trial is an unacceptably high risk one.

¹⁰ Medicines Australia, *Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Trial*, Paragraph 1.1.

- ▶ Certain clinical trials insurance policies provide blanket or inclusion cover and do not require an insured to notify the insurer of the details of each clinical trial they may conduct. In relation to this type of policy, an insured may assume that all the clinical trial activities (often of a particular defined class or type) will be covered by the relevant policy. The insurer will only require the insured to report on its clinical trial activity (including details regarding the number of clinical trials and the number clinical trial participants) at the end of the insured period. However, where a clinical trial is deemed high risk (for example, a first time in human clinical trial), the insurer may require the insured to provide specific notification for an assessment as to whether it would be included under the insurance coverage.
- ▶ Most insurers will require notification of the details of clinical trials to be conducted by an insured if the insured holds a no fault insurance policy. The rationale behind this appears to be that because a no fault policy will provide compensation in the absence of proving fault or negligence, the insurer's potential exposure may be higher.
- ▶ Commercial insurers generally do not impose a requirement upon their insureds to obtain from another party with which they are conducting a clinical trial an indemnity in favour of the insured or evidence of the other party's insurance arrangements.
- ▶ While clinical trials insurance policies do not have any unique or unusual exclusions, some insurers will not cover certain, high risk clinical trials. One example given was any clinical trial that involved the use of thalidomide.
- ▶ None of the commercial insurers indicated that there was any condition in their clinical trials insurance policies that required an insured to have a clinical trial reviewed by its own HREC. At least one commercial insurer indicated that such a condition would be unusual in the Australian insurance market. However, insurers do have an expectation that their insured will otherwise comply with all legal and regulatory requirements, including having the clinical trial reviewed by a properly constituted HREC.

Issues identified by insurers

The commercial insurers that were consulted did not identify any issues that might act as an impediment to national streamlined ethical and governance processes for clinical trials. For example, this review did not identify any insurer or insurance policy that requires its insured to have a clinical trial reviewed only by that insured's HREC or which excludes insurance cover if the insured accepts ethical review performed by an HREC external to the insured, whether in the public or private sector.

In general, the commercial insurers that were consulted indicated that they would welcome and support a standardised national approach to indemnity and insurance arrangements for clinical trials.

4.2 Private health sector bodies that conduct clinical trials

Private health services and other private sector bodies (other than universities)

Private health sector entities generally obtain insurance cover for their clinical trial activities from commercial insurers. This review did not identify any entity in this sector which self-insured or obtained indemnity protection by way of some other means.

The issues discussed in section 4.1 are relevant to the insurance arrangements effected by this sector to protect against liabilities incurred in the course of conducting clinical trials. In addition to those issues, other relevant issues regarding the clinical trial indemnity and insurance arrangements effected by this sector include the following:

- ▶ Numerous private health sector entities purchase general liability and no fault insurance for clinical trials. Private health services operators will typically purchase a policy or policies that cover their entire group.
- ▶ The entities consulted reported that they were either required to submit details of each proposed clinical trial to their insurer or were simply required to notify the insurer in accordance with the procedures outlined in section 4.1.
- ▶ Many private health sector entities indicated that they have a close and cooperative relationship with their insurer in relation to clinical trials insurance. The impression conveyed by the entities that were consulted is that commercial insurers that provide clinical trials insurance have a good understanding of the issues concerning clinical trials and are generally viewed as enablers of clinical trials, rather than inhibitors of them.
- ▶ While the insurance arrangements effected by private sector entities ordinarily covered researchers who were employees, in most cases they did not cover researchers who were not employees. Many researchers in private health services will be not employees. For example, medical practitioners are not usually employed by a private health service – they have an appointment which enables them to practise privately within that health service. Researchers that are not employees are required to have in place professional indemnity or medical indemnity insurance that includes coverage for clinical trials as a condition to participate in the conduct of a clinical trial. The researcher must then provide evidence to the private health service that they have in place such insurance.

Further, if a person who is not an employee is involved in the conduct of a clinical trial, some private health services require that person to be supervised by an employee of the health service. The level of supervision that is required is variable. In some cases, a non-employee may not be permitted to act as the principal investigator of the clinical trial.

A small number of private health services that were consulted indicated that there may be circumstances where a non-employee researcher is covered under the private health service's insurance arrangements. This coverage may be provided in circumstances where the clinical trial is considered to be low risk or if the research is non-invasive. The existence and nature of such coverage would of course depend on the terms of the private health service's insurance policies.

- ▶ The indemnity and insurance requirements imposed by private health services on other parties involved in the conduct of clinical trials are variable. These requirements are largely driven by the internal policies of the relevant entity - some have well developed and detailed formal policies, while others rely on a case-by-case assessment of the clinical trial to determine what, if any, requirements should be imposed on the other participating party.

For commercially sponsored clinical trials, a number of private health services make use of the standard CTRA (for commercially sponsored studies) and the MAI Standard and MAI HREC. For example, a private health service entity will require a commercial sponsor to provide an MAI Standard in favour of that entity or, where its HREC has been utilised to provide ethical review, an MAI HREC. In some cases, these documents have been modified by the private health service to accommodate its specific requirements.

For CRG studies, some private health services will similarly make use of the relevant Medicines Australia standard CTRA. Accordingly, they will adopt the indemnity and insurance provisions and requirements set out in that CTRA.

The position regarding investigator initiated studies is more variable and flexible.

The issues regarding obtaining an indemnity from a collaborator and requiring a collaborator to provide evidence of its insurance arrangements are usually governed by commercial considerations which, in turn, are affected by factors such as the risk profile of the study and the status and identity of the collaborator. For example, one large private hospital indicated that it does not require any not for profit entity involved in an investigator initiated study or any CRG (in relation to a CRG study) to provide evidence of its insurance arrangements.

In relation to imposing insurance requirements on entities with which they conduct clinical trials, private health services often use as a guide the insurance requirements prescribed by the relevant State or Territory government or agency in their respective jurisdiction for clinical trials conducted in the public sector. There are many practical reasons for doing so, including the fact that the entities with which they collaborate will be familiar, and readily comply, with those requirements.

Of course, unlike public health services, a private health service is not obligated to follow State or Territory government requirements and may develop its own. A private health service has discretion, for example, to permit a commercial sponsor or a collaborator to have in place insurance arrangements with lower limits of liability than those that are imposed in the public sector (subject always, of course, to the applicable requirements of the National Statement and the GCP Guideline). Conversely, requirements imposed in the private sector may be more onerous. One large private hospital group indicated that, as a matter of policy, it requires other parties with which it conducts clinical trials to have in place no fault insurance, as well as general liability insurance – it imposes this requirement in relation to commercially sponsored, CRG and investigator initiated clinical trials conducted at its hospitals.

- ▶ Peak or representative bodies in the private health sector do not have any formal policies and do not provide any guidance to their members in relation to indemnity or insurance arrangements for clinical trials, or even more broadly, in relation to ethical review or governance arrangements in clinical trials. The bodies that were consulted indicated that it was up to their individual members to develop their own policies and procedures around these issues.

Other issues concerning the conduct of clinical trials by private health services that may impact on a national approach

The following issues concerning the conduct of clinical trials in the private health sector may be relevant to a national approach, even though they do not directly concern indemnity and insurance arrangements.

- ▶ The acceptance by a private health service of ethical review by an HREC that is external to them is variable.

In a number of cases, private health services reported that they will readily accept such review and all that may be required (for the purposes of ethical approval) for the clinical trial to proceed at that health service is evidence of the external HREC's approval.

In other cases, private health services reported that they do not accept review performed by an external HREC, notwithstanding that their insurer does not impose such a requirement on them. The reasons cited were varied and included the following: that it was a matter of policy; that they did not have confidence that an external HREC would properly review the research; that clinical trials management in the private sector is different to that in the public sector; or that it was a simply a longstanding practice.

- ▶ A streamlined approach to ethical and governance review of clinical trials would have to take into account any religious or philosophical principles relevant to particular private health services. For example, private health services in the Catholic sector identified that they could only accept HREC review performed by an external entity if it had regard to, and had incorporated where appropriate, a consideration of the relevant principles of the Catholic faith.

Universities

The universities that are involved in the conduct of clinical trials usually do so in collaboration with a health service (which in the majority of cases is public) or a research institute. The number of clinical trials being conducted by universities independently is exceedingly low. The obvious reason for this is that universities do not have patients. Nevertheless, to the extent of their involvement in clinical trials, universities require insurance coverage for those activities.

There are essentially two types of indemnity and insurance arrangements that exist in the university sector with respect to clinical trial activities – taking out membership with Unimutual or purchasing insurance from a commercial insurer. The university sector does not generally have access to the State or Territory based indemnity or insurance arrangements that provide protection to the State or Territory public sectors.

1 Unimutual membership

Unimutual is a discretionary mutual; it is created and funded by its members as an alternative to insurance. Unimutual operates on not-for-profit principles and membership is available to universities and other higher education and research institutions. However, the granting of membership is at the discretion of the Unimutual Board.

Of the thirty eight universities in Australia, twenty four are current members¹¹ of Unimutual Limited (trading as Unimutual).

Unimutual offers members four core classes of discretionary protection: property protection, general and products liability protection, professional liability protection and directors and officers liability protection. These classes of protection give each member the right to claim protection on behalf of itself, an affiliate or a 'protected person' in relation to a liability to which the particular protection relates.

Unimutual also offers members 'General Clinical Trials Protection'. General Clinical Trials Protection gives members the right to claim protection on behalf of the member, an affiliate or a protected person for legal liability to pay damages or compensation as a result of any claim made by research subjects for bodily injury caused by any act, error or omission in connection with clinical trials undertaken by the member within Australia after 21 May 1997.

Interestingly, a number of Unimutual members have opted to purchase clinical trials insurance from a commercial insurer, rather than taking up General Clinical Trials Protection with Unimutual. The reasons that were cited to explain this approach included cost and historical factors.

Further relevant issues regarding General Clinical Trials Protection provided by Unimutual include the following:

- ▶ The protection provided by Unimutual is discretionary. Members do not have the same rights as they would if they purchased a contract of insurance. However, Unimutual will

¹¹ The list of current members can be found at <http://www.unimutual.com/view/membership/member-list>.

ordinarily provide protection in relation to a claim if it falls within the relevant protection's wording. In other words, in most circumstances, it will act as if the claim had been made under a traditional insurance arrangement.

- ▶ The protection extends to 'protected persons' which includes officeholders and employees of a member. It also includes any person who may not be an employee of a member who is engaged or appointed by a member to undertake or participate in activities regarding a clinical trial.
- ▶ A member who takes up 'General Clinical Trials Protection' will have the benefit of general liability (for example, negligence) cover and no-fault cover.
- ▶ The limits of protection range from \$5 million for any one claim to \$20 million for any one claim. However, the average limit of protection taken up by members is \$10 million any one claim.
- ▶ Unimutual requires members to provide a 'snapshot' of their clinical trials activities - which includes clinical trials conducted in the preceding year and clinical trials proposed to be conducted in the forthcoming year - at the time of renewing their protection. Members must provide details of the number of clinical trials and the number of participants involved in those clinical trials. Members are not otherwise required to notify Unimutual of specific clinical trials undertaken during the course of a protection year.
- ▶ However, members must notify Unimutual to confirm protection in relation to:
 - clinical trials involving research subjects who are either pregnant or breastfeeding; and
 - clinical trials undertaken in the USA or Canada.
- ▶ There is no restriction regarding a member's acceptance of ethical review by an HREC external to the member; the only requirement is that a properly constituted HREC has approved the relevant clinical trial.

2 Purchase of insurance from a commercial insurer

The other option for a university is to purchase clinical trials insurance from a commercial insurer. In that case, the considerations discussed above for private sector institutions are relevant in relation to those arrangements.

Other relevant issues concerning the indemnity and insurance arrangements for clinical trials of universities

The further issues set out below were identified as being relevant to a proposed national approach for clinical trials ethical review and governance processes.

- ▶ The indemnity and insurance requirements that universities impose on other parties with which they collaborate on clinical trials are variable. A university may require a collaborator (for example, another university, a research institute, a hospital, or a commercial sponsor) to provide evidence of its insurance arrangements or to provide a contractual indemnity in favour of the university.

A university will usually consider the indemnity and insurance requirements required of a clinical trials collaborator on a case by case basis. It is unusual for a university to use the Medicines Australia forms of indemnity or the Medicine Australia standard CTRAs. The major reason for this is that those documents refer to research participants being 'patients' of the institution conducting a clinical trial – universities do not have patients. However,

there is at least one example of a university requiring a commercial sponsor to provide an MAI Ethics in favour of its HREC where its HREC provides ethical review of a clinical trial being conducted by a health service that is separate to the university.

- ▶ A number of universities have a policy that prohibits a university researcher from undertaking at the university's premises a clinical trial that has been approved by an external HREC, unless the university's HREC has also approved that research.

However, it was reported that the usual practice appears to be that a university HREC will readily accept the decision of an external HREC if that HREC is part of or affiliated with a public hospital that conducts clinical trials. In practice, the University HREC will merely 'rubber stamp' such external HREC's approval. In those circumstances, it appears that universities have sufficient confidence that a HREC of a public health service (with which the university typically has some type of affiliation or collaboration arrangement) possesses the requisite expertise and experience to adequately review a clinical trial.

Medical Research Institutes independent of universities and health services

The involvement of MRIs in clinical trials is variable. Most MRIs do not have their own patients; those that are involved in the conduct of clinical trials usually do so in collaboration with a health service which gives them access to patients.

The indemnity and insurance arrangements of MRIs fall into two broad categories:

1 Purchase insurance from a commercial insurer

Where an MRI purchases insurance from a commercial insurer, the considerations discussed above for commercial insurance are relevant.

2 Obtain insurance through a State or Territory insurance or indemnity provider

An MRI may also be able to obtain insurance cover for its clinical trials activities through the relevant State or Territory indemnity or insurance provider. This may be the case even where the MRI is a private entity. Of course, the relevant State or Territory indemnity or insurance provider is not obligated to provide such cover to private entities (as it is required to do for public entities) and whether it does is at its discretion.

If an MRI has obtained indemnity or insurance cover through a State or Territory indemnity or insurance provider, it will typically be on similar terms and conditions imposed by that provider on public sector bodies conducting clinical trials and also subject to the same requirements. For example, where the provider requires a public sector insured to obtain an MAI Standard for a commercially sponsored clinical trial, it will most likely require an MRI that it insures to do likewise.

Other relevant issues concerning the indemnity and insurance arrangements for clinical trials of MRIs

MRIs do not ordinarily conduct clinical trials independently because, similar to universities, they do not have patients of their own. MRIs participate in clinical trials activities in collaboration, or under some other type of arrangement, with hospitals and health services. Further, for these reasons, MRIs may not have their own HREC. Generally, MRIs will rely on ethical review conducted by an external HREC - the most common arrangement would be the HREC of the health service(s) with which they collaborate.

4.3 Sponsors of clinical trials

An analysis of the indemnity and insurance arrangements for clinical trials in the public and private sectors is incomplete without a consideration of how these arrangements affect sponsors

of clinical trials. It is important to consider the position of sponsors because, amongst other things, public and private sector health services that conduct clinical trials will often require a sponsor to provide an indemnity in favour of the health service and to provide evidence of the sponsor's insurance arrangements in relation to that clinical trial.

There are three broad categories of sponsors of clinical trials - commercial sponsors, a CRG, or another entity or institution that is neither a commercial sponsor nor a CRG. The relevant indemnity insurance issues concerning each category of sponsor is discussed below.

Commercial sponsor

A commercial sponsor of a clinical trial is most typically a pharmaceutical or device company. This category also includes a clinical trial where a CRO is named as sponsor.

The insurance requirements of a commercial sponsor are driven by two considerations:

- ▶ The commercial sponsor's approach to risk management. More particularly, the commercial sponsor's desire to protect itself from liabilities that it might incur in the course of its activities and also in acting as sponsor of a clinical trial. To this extent, a sponsor may seek to effect appropriate liability insurance including for coverage for products liability, professional indemnity and clinical trials.
- ▶ The obligation of a commercial sponsor to provide the following:
 - An indemnity in favour of the health service that conducts the sponsored clinical trial. Ordinarily such indemnity will be in the form of the MAI Standard and/or the MAI HREC.
 - Evidence that the commercial sponsor has in place insurance arrangements that meet the requirements prescribed by the applicable State or Territory or the relevant private health service.

In order to meet these obligations, a commercial sponsor will usually need to have in place the appropriate classes of liability insurance and no fault insurance.

It is widely known that the majority of commercial sponsors would welcome processes that standardise these requirements across the jurisdictions and across the public and private sectors. Medicines Australia indicated that it broadly supports any national approach that reduces industry's 'regulatory burden' in connection with clinical trials.

CRG

The indemnity and insurance requirements for clinical trials sponsored by CRGs are less well defined and more variable in comparison to those for commercially sponsored clinical trials. CRGs are less likely to be required to provide an indemnity in favour of a health service that is conducting a clinical trial and are also less likely to provide evidence of their insurance arrangements.

There is a perception amongst certain health services in the public and private health sectors that CRGs do not have any insurance in place. This is one of the reasons that was suggested during the course of the review to explain why health services rarely request a CRG to provide an indemnity or evidence of its insurance arrangements. The author suggests that this perception is incorrect. The author is aware that several CRGs have in place liability insurance covering their activities, including in relation to clinical trials. Indeed, a number of health services consulted during this review indicated that occasionally a CRG will provide evidence of its insurance arrangements, even where that evidence has not been requested.

Other sponsors

Sponsors of clinical trials that are not a commercial sponsor or a CRG include public and private health services, MRIs, universities, clinics and individual practitioners. Most investigator initiated studies are likely to have a sponsor that falls into one of these categories.

The insurance arrangements that such a sponsor will have in place to protect itself from liabilities it might incur in connection with its involvement in a clinical trial will usually be consistent with the description of the insurance arrangements for those entities described in section 3 and section 4 of this report.

The indemnity and insurance arrangements that a health service at which a clinical trial is being conducted may require such sponsor to provide are variable and will depend on the identity of the sponsor. Where the sponsor and the health service conducting the clinical trial are both public health services within the same jurisdiction, the health service is unlikely to request much (if anything) in the way of an indemnity or evidence of the sponsor's insurance arrangements as both entities would be covered by the same insurer or indemnity provider. Where one party is a private-sector entity and the other is a public sector entity, greater consideration is likely to be given by the health service conducting the clinical trial to the indemnity and insurance obligations imposed on the sponsor.

5 Discussion of issues that may affect a national approach

This review has identified that there are variations between the States and Territories, between the public and private sectors and across the private sector, in relation to indemnity and insurance arrangements and practices for clinical trials. However, more significantly, the review has identified that there are also many fundamental similarities. The principles that underpin these arrangements are common across the jurisdictions and across the public and private sectors. These principles are:

- ▶ ensuring that an entity that conducts a clinical trial, whether on its own or with a collaborator, has in place adequate indemnity or insurance arrangements which will protect it from any liability that arises in the course of conducting that trial; and
- ▶ if a collaborator is involved, imposing certain indemnity and insurance obligations on the collaborator so that the collaborator has insurance to meet any claim made against it and so that the entity conducting the trial may be protected against claims that result from the collaborator's (negligent) conduct.

The indemnity and insurance protection afforded to public health services by their respective State or Territory indemnity or insurance provider comprehensively covers their clinical trials activities. This is the case regardless of whether such protection comes in the form of a traditional insurance arrangement, an indemnity fund or under some other arrangement. This review has identified that the State and Territory indemnity and insurance providers do not generally impose any special conditions, restrictions or exceptions in relation to cover for clinical trials that might inhibit a national approach to ethical review and governance arrangements for clinical trials.

The clinical trials insurance products available to private sector health services similarly provide comprehensive cover for clinical trial activities. Again, this review has not identified any features of those insurance products that might inhibit a national approach to ethical review and governance arrangements for clinical trials.

In relation to the imposition of obligations concerning indemnity and insurance arrangements on parties that collaborate with health services in the conduct of clinical trials, this review has identified that there is a trend of increasing uniformity and standardisation of such requirements across the public sector in the States and Territories. Certain governance arrangements have more or less been adopted uniformly across the States and Territories - the best examples of this are the uptake and use of the Medicines Australia standard CTAs for commercially sponsored and CRG sponsored clinical trials and the MAI Standard and the MAI HREC for commercially sponsored clinical trials. Another example is the adoption across the jurisdictions of similar levels of liability insurance limits for commercial sponsors to have in place for clinical trials. Further, this review has also identified that the private health sector has adopted many of the practices concerning indemnity and insurance that were developed and exist in the public health sector. For example, many private health services make use of the Medicines Australia standard CTAs and the MAI Standard and the MAI HREC.

As has been detailed in this report, a number of States and Territories have in place a formal policy or guideline which may act as an impediment to a national approach to ethical review and research governance arrangements. Those policies prevent a public health service within that jurisdiction from accepting ethical review performed by an HREC external to that jurisdiction. Further, even in certain States or Territories where no such policy exists, the custom or practice concerning local ethical review sometimes results in the same outcome.

It is apparent that there is some confusion in certain jurisdictions about the source of such a restriction – for instance, whether it was a policy of the public health service, the jurisdiction's health department or the jurisdiction's insurer or indemnity provider. In one case, a stakeholder indicated that the restriction on accepting a private HREC's review originated from the jurisdiction's insurer, while the insurer indicated it imposed no such restriction. The author observed that stakeholders often make erroneous assumptions about these types of issues.

Similarly, in the private sector, certain private health services described comparable restrictive policies or practices. In nearly all cases, these were internal policy decisions made by the organisation or the organisation's parent entity.

The existence of these restrictive policies and practices is explained to a great measure by a lack of confidence in the ethical review or governance arrangements of parties external to that public sector jurisdiction or the relevant private sector entity. In particular, stakeholders in the public sector justified such a position on the basis that entities in the private sector simply lacked (and moreover some suggested they could not acquire) the requisite experience and expertise in clinical trials. Stakeholders in the private sector with restrictive policies or practices justified these on the basis of similar apprehensions about whether the ethical review and governance processes of other entities would meet their own standards or would have taken into account their circumstances.

A national system that assesses prospective participants and ensures they meet a certain standard should provide an assurance that overcomes these objections. The national certification scheme for institutional ethical review processes developed by the NHMRC is an example of such a system. However, at least one stakeholder expressed scepticism about accepting ethical review from a private sector entity even if that private sector entity had been certified by the NHMRC. The author suggests this is an unreasonable view and, in any event, it would appear that it is held by a minority.

A number of the States and Territories that have no formal policy in relation to accepting review performed by an HREC of a private entity indicated that they had not yet thoroughly considered

the issue. The likelihood that such jurisdictions might favourably consider doing so may be increased if a workable, streamlined approach is presented to them.

The NMA system provides an example of a streamlined approach that is workable and, perhaps more significantly, has been accepted as being workable by the States and Territories. NMA has its limitations – it concerns only ethical review and does not permit a private sector entity to act as a reviewing site. Notwithstanding those limitations, the NMA system demonstrates that the States and Territories have the capacity to cooperate on streamlined approaches to issues in clinical trials and that any jurisdictional differences or impediments, whether real or perceived, can be overcome. It also demonstrates that there is the capacity to include the private sector in such a system, albeit, in the case of NMA, on a limited basis. Further, NMA demonstrate the possibility of a wider use of mutual acceptance for all human research across the public and private sectors.

The State and Territory public sector indemnity and insurance arrangements seemingly provided no barrier to NMA. Moreover, acceptance of NMA was likely facilitated by the fact that it utilises an uncomplicated approach to indemnity and insurance – it requires the States and Territories to make no changes to their existing arrangements. It is submitted that this approach should be instructive to any proposed national framework. In other words, acceptance of a national, streamlined approach to ethical review and governance arrangements may be aided by an approach that is sensitive to and utilises the existing indemnity and insurance processes and arrangements, or at least causes minimal disturbance to those processes and arrangements.

Of course, including the private sector in a national system may be more challenging. While the States and Territories may have sufficient confidence in each other's indemnity and insurance arrangements to support the apparently minimalist indemnity and insurance approach under NMA, they may be less likely to demonstrate such confidence in the private sector. To some extent this may be because the private sector is made up of a diverse group of entities with variable activities and varying levels of experience and expertise in clinical trials, as well as varying levels of insurance.

However, many private sector entities conducting clinical trials generally have clinical trials liability insurance in place; many also have established practices and procedures around the initiation and management of clinical trials. If there is a lack of confidence in the private sector's indemnity and insurance arrangements clinical trials, this may be a perception which arises from a lack of understanding regarding the private sector's clinical trial practices and arrangements. It is submitted that it may not be exceedingly difficult to establish a reasonable, baseline level of insurance which would qualify a private sector entity for unrestricted participation in a national system and which would be acceptable to the public sector participants of that system. A comprehensive national approach must extend the same participation rights to the private sector. If private sector participants can demonstrate they meet the requisite ethical and governance standards, there can be no sustainable basis to deny them such participation rights.

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This report has been prepared by Rallis Legal for the NHMRC.



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Schedule 1

Indemnity and insurance providers and arrangements for public sector research

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
<i>Indemnity and insurance provider</i>	Australian Capital Territory Insurance Authority (ACTIA), an authority established under the <i>Insurance Authority Act 2005</i> (ACT).	Treasury Managed Fund (TMF), a self-insurance scheme of the NSW Government.	The Northern Territory Government has in place a self-insurance program that covers the risks of the Territory's agencies.	Queensland Government Insurance Fund (QGIF), a self-insurance managed fund of the Queensland Government.	South Australian Government Captive Insurance Corporation (SAICORP), a captive insurer of the South Australian Government.	Tasmanian Risk Management Fund (TRMF), a self-insurance arrangement of the Tasmanian Government.	Victorian Managed Insurance Authority (VMIA), an authority established under the <i>Victorian Managed Insurance Authority Act 1996</i> (Vic).	RiskCover, a self-insurance fund of the Government of Western Australia.
<i>Type and level of cover/insurance that applies to research activities</i>	<i>Professional indemnity and medical malpractice insurance.</i> Cover for Research activities may fall within either the professional indemnity or medical malpractice component, depending on the context of the claim. The amount of the limit is not disclosed by ACTIA.	TMF Statement of Cover states that it covers liability that includes, but is not limited to, public liability, products liability, professional indemnity, directors/officers liability and medical negligence. TMF is not a contract of insurance. The provision of cover is discretionary. Worldwide cover for all claims incurred on or after 1 July 1989 (or the date an agency joined the TMF) in respect of professional	<i>Public Liability</i> Cover for liability owed to a third party who suffers loss or damage by reason of an Agency's activities. There is no specified liability limit.	<i>Health litigation</i> Unlimited liability and amount insured. QIGF covers an Agency for all sums which the Agency shall become liable to pay in respect of claims made against it arising from the rendering of or failure to render medical or health services provided in the conduct of the Agency's activities and which results in bodily injury,	<i>Medical Malpractice</i> Level of cover \$100 million Each and every event deductible (Department of Health) \$1 million Each and every event deductible (SAICORP) \$11.5 million. <i>Public & Products Liability</i> Level of cover \$350 million.	<i>Medical Liability over</i> No specified limit. The TRMF will meet all liability claims costs (less any applicable excess) relating to an incident that occurred after an agency joined the TRMF. This includes cover for the amount that an agency is legally liable to pay to a third party and any claim investigation and legal fees.	<i>Medical Indemnity Master Insurance Policy</i> \$20 million each and every claim with an undertaking by the State of Victoria to indemnify an insured for claims exceeding that sum. <i>Professional Indemnity Insurance Policy (Health Sector)</i> \$20 million any one occurrence, inclusive of legal costs.	<i>Professional Liability and Medical Treatment Liability</i> \$300 million.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
		indemnity and medical negligence liability. No specified liability limit.		mental injury or death of a patient.			<i>Public and Products Liability</i> \$750 million any one occurrence for public liability. \$750 million any one occurrence and in the aggregate for products liability.	
<i>Who is covered?</i>	Agency, Agency employees, medical practitioners who are visiting medical officers, members of committees including the HREC, volunteers and non-employees serving on any committee of an Agency whilst performing their duties for and on behalf the agency.	Agency and employees of a TMF Agency, board members, directors and officers of a TMF Agency.	Agency and its employees. Contractors or consultants acting on behalf of an Agency are excluded but where a consultant is employed on an ongoing contractual basis, the Treasurer may approve their inclusion.	Agency, Agency employees, volunteers board members and committee members who 'at the time of the event or incident, have diligently and conscientiously endeavoured to carry out their duties (in accordance with Government policy on indemnity as amended from time to time).'	Institution that is a named insured, its employees and members of its HREC (including non-employees and volunteers)	<i>Medical liability cover</i> Public hospitals and public health facilities, doctors and other health professionals employed by the State, private doctors (visiting medical officers) treating public or private patients in a public facility, and University of Tasmania employees undertaking medical activities in a public hospital or other public health facility. The TRMF also provides liability cover to volunteers who are under the	<i>Medical Indemnity Master Insurance Policy</i> Institution that is a named insured, its employees providing health care services, registered medical practitioners providing health care services. <i>Professional Indemnity Insurance Policy (Health Sector)</i> Institution that is a named insured and includes any employee and any committee member. <i>Public and Products Liability</i> Institution that is a named insured	Agencies and their employees, volunteers, officers, secondees and medical students whilst performing their official duties for and on behalf the agency.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
						direct control of an agency and there is a high level of agency supervision. While there is a view that volunteer HREC members are covered, there remains some uncertainty about this.	and includes any executive, officer, employee, volunteer, or committee member.	
<i>How is HREC indemnified?</i>	As members of a committee of an Agency, HREC members are indemnified by ACTIA.	All appointed members of HRECs constituted by a TMF Agency are covered under Directors' & Officers' Cover by the TMF.	The NT Government provide indemnity for all registered members of HREC in the NT, both DOH employees and non-DOH employees.	HREC members would appear to fall within the designation of 'committee members'.	HREC members included in reference to covered parties.	Single HREC (which is jointly sponsored by the Department of Health and Human Services and the University of Tasmania) reviews all clinical trials conducted in the Tasmanian public health services.	HREC members would appear to fall within the designation of 'employee' or 'committee member' or 'examining body' of an insured (as the case may be).	HREC members are likely to fall within the designation of 'employees' or 'volunteers' (as the case may be).
<i>Does the insurer/indemnity provider indemnify or provide cover to the agency/health service/organisation in relation to all types of clinical trials – that is, commercially sponsored, investigator initiated and collaborative</i>	Yes	Yes.	Yes	Yes	Yes	Yes	Yes	Yes

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
<i>group studies?</i>								
<i>Are there any specific insurance or indemnity requirements regarding third parties which are involved in the conduct of the clinical trial?</i>	Yes Refer to Schedule 2.	Yes Refer to Schedule 2.	Yes Refer to Schedule 2.	Yes Refer to Schedule 2.				
<i>Does the insurer/indemnity provider have any identified additional insurance or indemnity requirements that apply to multi-centre research or research that is the subject of single ethical review?</i>	No	No	No	No	No	No	No However, the VMIA Guidelines refer to National Mutual Acceptance (between Victoria, NSW, SA and Queensland) and appear to provide implicit support for this program. ¹²	No
<i>Does the insurer/indemnity provider have explicit requirement or prohibition regarding acceptance of HREC review that is performed by a HREC of another body, whether in the public sector or private sector?</i>	No	No	No	No	None could be identified. However, representatives of SA Health (rather than of the insurer) suggested the insurer agrees with SA Health's approach of not accepting external HREC review.	No	No The VMIA guidelines merely provide that: ' <i>Prior to the commencement of any proposed clinical trial, VMIA clients must ensure that the clinical trial has been ethically and scientifically reviewed by a HREC in accordance with</i>	No

¹² VMIA Clinical Trials – Insurance and Risk Management Guidelines (Version 2, September 2012) page 5.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
							<i>the principles set out in the NHMRC's National Statement on Ethical Conduct in Human Research</i> ¹³	

¹³ VMIA Clinical Trials – Insurance and Risk Management Guidelines (Version 2, September 2012) page 4.

Schedule 2

Indemnity and insurance requirements for clinical trials in State and Territory public sectors – obligations imposed on third parties

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
Indemnity and insurance requirements for commercially sponsored clinical trials.	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements. 	<p>Commercial sponsor must provide:</p> <ul style="list-style-type: none"> MAI Standard and/or MAI HREC in favour of relevant organisations. Evidence of its insurance arrangements.
	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> \$20 million for each and every occurrence and \$20 million in the annual aggregate 'against a class of insurance appropriate for the risk associated with the research'. 	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> \$20 million for any one occurrence and in the annual aggregate. Deductible/SIR must be less than \$25000. 	<p>There appear to be no prescribed minimum requirements that the sponsor's insurance must meet. These are reviewed on a case by case basis. It was reported that cover in the amounts of \$10 million any one occurrence and \$20 million in the aggregate were considered sufficient for most studies.</p>	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> Clinical Trial/Products liability not less than \$10 million per claim. Public liability not less than \$10 million per claim. Professional indemnity not less than \$10 	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> Products/Public liability not less than \$10 million per claim and in the annual aggregate. Professional indemnity not less than \$10 million per claim and in the annual aggregate. No requirement 	<p>Minimum requirements for commercial sponsor's insurance arrangements are variable, although the following limits are deemed acceptable:</p> <ul style="list-style-type: none"> Public liability insurance with a limit of at least \$20 million. Professional indemnity insurance with a limit of at least \$10 	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> \$10 million for any one occurrence and in the annual aggregate. Deductible/SIR must be less than \$25000. 	<p>Minimum requirements for commercial sponsor's insurance arrangements:</p> <ul style="list-style-type: none"> Public liability not less than \$5 million. Clinical trial / product liability and professional indemnity of at least \$10 million any one claim and in the aggregate. Liability

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
				million per claim.	regarding the deductible.	million to \$20 million. <ul style="list-style-type: none"> No requirement regarding the deductible. 		insurance for the sponsor's contractual obligations of at least \$10 million any one claim and in the aggregate. <ul style="list-style-type: none"> Deductible/SIR must be less than \$25000, although this is not RiskCover's requirement.
Indemnity and insurance requirements for collaborative research group clinical trials.	A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)	NSW Health requires public health organisations to ensure that such sponsors have indemnity or insurance arrangements that are sufficient to cover their sponsor-related liabilities associated with clinical trials. ¹⁴ A general requirement for each party to maintain such insurances as are reasonably available and necessary to	None specified.	A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)	A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)	None specified.	A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)	A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)

¹⁴ NSW Health Policy Directive: *Clinical Trials - Insurance and Indemnity* (25 January 2011), page 8.

	ACT	NSW	NT	QLD	SA	TAS	VIC	WA
		provide indemnity to it in relation to any liability which it may incur in conducting the study. (This requirement arises through the use of the Medicines Australia standard CRG CTRA.)						
Indemnity and insurance requirements for investigator initiated clinical trials.	None specified.	NSW Health requires public health organisations to ensure that external not for profit sponsors have indemnity or insurance arrangements that are sufficient to cover their sponsor-related liabilities associated with clinical trials. NSW Health, through TMF, provides cover for the sponsor-related liabilities of clinical trials initiated by NSW Health Staff (a defined term). ¹⁵	None specified.	No specific indemnity requirements. A general requirement that <i>'(e)very research project that includes a non Queensland Health entity requires a statement regarding indemnification. In some instances, Queensland Health will accept a mutual indemnification where each party indemnifies its own personnel and site.'</i> ¹⁶	No specific requirements.	No specific indemnity requirements.	No specific indemnity requirement. A general requirement for each party to maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the study.	Where the private HREC review concerns a non-commercial trial, the private HREC would need to provide evidence that it holds sufficient and appropriate insurance.

¹⁵ NSW Health Policy Directive: *Clinical Trials - Insurance and Indemnity* (25 January 2011), pages 7-8.

¹⁶ Queensland Health, *Standard Operating Procedures for Queensland Health Research Governance Officers* (Version 5, November 2013), page 27.