



Australian Government

National Health and Medical Research Council

## Insurance and indemnity for multi-centre research

This document was prepared by NHMRC in 2011 under the Harmonisation of Multi-centre Ethical Review (HoMER) initiative, to provide advice on insurance and indemnity related to multi-centre ethics review. As this document is more than five years old, it may not reflect current advice.

A second review of insurance and indemnity arrangements for multi-centre clinical trials was conducted by NHMRC in 2015. The report and findings of the review have been published on the NHMRC website.

### Introduction

The *National Statement on Ethical Conduct in Human Research, 2007 (the National Statement)* states that “Whenever more than one institution has a responsibility to ensure that a human research project is subject to ethical review... each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review.”

As part of the National Approach to Single Ethical Review (the National Approach) a set of tools was developed to encourage the acceptance of an ethics review by all institutions participating in a multi-centre study. The National Approach identified the need for a better understanding of the responsibilities that each institution participating in a given multi-centre study may have in relation to legal protection for those conducting the ethics review.

This document will assist institutions to meet their obligations under the National Statement that “Institutions should provide an assurance of legal protection to all those involved in the ethics review of research, for liabilities that may arise in the course of *bona fide* conduct of their duties in this capacity” (s5.1.9).

**Disclaimer:** *This document was prepared by NHMRC and state and territory health agencies in 2011 to provide advice on insurance and indemnity related to multi-centre ethics review. This document discusses generalised and consistent processes and is based on input from insurers of institutions carrying out research in both the public and private sectors. As this document is more than five years old, the information provided may not reflect current advice. Please contact your institutional insurer for advice on how these comments may apply to your specific insurance and indemnity arrangements.*

## Definitions for indemnity and insurance

- **Institution:** an institution which has established a HREC as per sections 5.1.26 – 5.1.28 of the National Statement.
- **HREC or Human Research Ethics Committee:** an ethics review body that has been established in accordance with the National Statement and conducts the ethics review of multi-centre research.
- **Certification:** an independent assessment of the conformance of institutional ethics review processes that, when granted, confirms their alignment with a nationally agreed set of criteria.
- **Accepting institution:** an institution that uses the outcome of an ethics review of a HREC established by another institution to decide whether or not to participate in a given study.
- **Accepting:** refers to the use of the outcome of an ethics review to inform an institution's decision about whether or not to participate in a given study.
- **Single ethics review:** the ethics review undertaken by a HREC operating according to a certified institutional process for the purpose of providing an opinion about the ethics and scientific status of a research protocol, to enable institutions to decide whether or not to participate in a given study.
- **Indemnity:** a legally binding promise whereby a party undertakes to accept the risk of loss or damage another party may suffer.
- **Insurance:** a legal contractual method of risk transfer, by one entity to another, in order to protect or transfer its liabilities that may arise through the course of its activities. The arrangements are defined through a procured policy or product, and are subject to terms and conditions including limitation on aggregate liability and deductible levels.
- **Duty of care:** a legal obligation imposed on an individual requiring that they adhere to a standard of reasonable care while performing any acts that could foreseeably harm others.
- **Negligence:** the commission of an act that a prudent person would not have done or the omission of a duty that a prudent person would have fulfilled, resulting in injury or harm to another person.

## General indemnity and insurance information

### 1. Are there guidelines for HRECs to ensure respect and protection of research participants?

Yes. All Australian HRECs operate using the National Statement in which respect for and protection of research participants is paramount.

### 2. What risk mitigation strategies should be adopted by an institution if it participates in multi-centre research?

It is important for institutions to ensure that they have appropriate research governance processes in place, including adequate insurance arrangements, to enable them to decide whether they wish to participate in a proposed multi-centre study. The stringency of research governance arrangements will reflect the level of risk that an institution determines is appropriate for all its activities related to research.

### 3. What happens if a researcher, at an institution participating in a multi-centre research study, doesn't follow the approved protocol and a research participant claims they have been injured as a result?

There may be grounds for a claim against the researcher and their employer who would need to legally defend or settle any such claim. There would be no recourse against a HREC if the claim for harm was due solely to the alleged negligence of the researcher (i.e. that the researcher deviated from the approved protocol) with no alleged contributory negligence by the HREC.

#### **4. Are State and Territory Governments going to sue each other because of claims of harm to research participants in multi-centre research where institutions have used a single ethics review that was carried out in another jurisdiction?**

It is legally possible for an accepting institution, or a research participant from an accepting institution, to make a claim against an HREC on the basis of the HREC's alleged negligence. In that case, it is likely that the HREC's institution would be named as a co-defendant in any claim against the HREC. If the institution is a public health organisation then the relevant state or territory insurer would become involved in any action brought against the institution.

#### **5. Will commercial insurance providers cover non-government institutions (e.g. medical research institutes or universities) for participating in multi-centre research involving a single ethics review?**

A commercial insurer will provide cover for multi-centre research based on an assessment of an institution's risk related to their participation in multi-centre research. It is prudent for a private institution to clarify their insurance arrangements with their insurer.

#### **6. Why isn't there a single national insurance arrangement covering all ethics review of Australian research?**

Existing state and territory and/or commercial insurance and indemnity arrangements provide cover for liabilities associated with research activities, including single ethics review. This allows institutions to have local arrangements in place to best suit their individual governance and administrative requirements.

#### **7. Does the HREC have any liabilities at law for their negligent acts or omissions that result in harm to participants?**

It is legally possible for a participant to make a claim against an HREC on the basis of the HREC's alleged negligence.

### **Institutions with certified ethics review processes**

#### **1. Does the institution's insurer need to be informed if the outcome of ethics reviews being carried out by its HREC will be used by other institutions?**

Yes. As with any contract of insurance, the institution should inform their insurer of any matter they know to be a matter relevant to the decision of the insurer whether to accept the risk and, if so, on what terms.

#### **2. Does the institution need to alter their existing insurance arrangements because their HREC is carrying out single ethics review?**

It is prudent for the institution to clarify with their insurer whether changes are required to their existing insurance arrangements.

#### **3. Who provides legal protection to the HREC undertaking a single ethics review?**

As per section 5.1.9 of the National Statement, the institution is obliged to provide assurance of legal protection to all those involved in ethics review of research, which would include outcomes of ethics review that may be used by multiple institutions or by a single institution. This legal protection is often provided in the form of an indemnity for liabilities that may arise in the course of *bona fide* conduct of their duties within single ethics review.

If reviewing a clinical trial protocol, a HREC may also be indemnified for any injury to a participant caused by the therapeutic drug or device under trial.

**4. What is the impact on the institution if an accepting institution is sued by one of its (i.e. the accepting institution's) research participants as a result of alleged negligent behaviour by the HREC?**

Any person may claim they have been harmed by their participation in a research study and seek compensation for that harm from the accepting institution where the research took place. For the HREC to be drawn into the claim there would need to be a direct connection established between the conduct of the ethics review and the alleged harm.

In the event that the HREC is found to be negligent, the institution establishing the HREC, rather than an accepting institution, would bear the liability of any claim for damages.

**5. What is the impact on the individual members of the HREC carrying out the single ethics review if the HREC is found to be negligent?**

Section 5.1.9 of the National Statement states that institutions should provide an assurance of legal protection to all those involved in ethics review of research, for liabilities that may arise in the course of *bona fide* conduct of their duties in this capacity.

Members should seek assurance from their institution on the scope of, and limits to (if any), the legal protection provided to them for conducting ethics reviews.

**6. Are the responsibilities of the HREC carrying out the single ethics review different compared to a HREC that is not carrying out single ethics reviews?**

No. The responsibilities for any ethics review body are described in the National Statement and they do not change regardless of how many institutions use the outcome of the single ethics review.

**7. Is there any difference in the 'duty of care' obligation of an institution towards research participants if the multi-centre study has been reviewed by its HREC and the outcome of the review has been accepted by other institutions?**

No. The 'duty of care' obligations of the institution are the same regardless of whether the outcome of the single ethics review has been accepted by other institutions.

## Institutions accepting the outcome of a single ethics review

**1. Does the accepting institution's insurer need to be informed if it accepts the outcome of ethics reviews being carried out by a HREC sitting outside of the accepting institution?**

Yes. As with any contract of insurance, the institution should inform their insurer of any matter they know to be a matter relevant to the decision of the insurer whether to accept the risk and, if so, on what terms.

**2. Does the accepting institution need to alter their existing insurance arrangements because they are using the outcome of an ethics review carried out by a HREC sitting outside of the accepting institution?**

It is prudent for the accepting institution to clarify with their insurer whether changes are required to their existing insurance arrangements.

**3. Does the accepting institution need to indemnify the HREC, sitting outside of the accepting institution, which is providing advice to it (i.e. the outcome of the single ethics review)?**

No. In line with the National Statement, the institution that establishes the HREC provides an assurance of legal protection to all those involved in ethics review of research, for liabilities that may arise in the course of *bona fide* conduct of their duties in this capacity.

**4. Does the acceptance of the outcome of a single ethics review from a HREC, sitting outside of the accepting institution, change the accepting institution’s risk profile?**

No. It is an accepting institution’s choice to participate in multi-centre research. This decision is based on the accepting institution taking into account all available information about the research proposal including, but not limited to, the outcome of a single ethics review.

**5. Is there any difference in the ‘duty of care’ obligations of the accepting institution towards research participants if the multi-centre study has been reviewed by a HREC sitting outside of the accepting institution?**

No. The ‘duty of care’ obligations of the accepting institution will not alter regardless of whether the research proposal was subjected to a single ethics review.

**6. Does the HREC have any liabilities at law for their negligent acts or omissions that result in harm to participants?**

It is legally possible for an accepting institution to make a claim against an HREC on the basis of the HREC’s alleged negligence.

## Sponsors of multi-centre research using a single ethics review

For the purpose of these questions the term “sponsor” can be defined as:

- One or more institutions
- One or more investigators (in which one or more institutions are usually the sponsor/s)
- A non-commercial organisation
- A commercial organisation, or
- A collaborative research group

**1. What indemnity does the sponsor of a multi-centre research study need to provide to the HREC carrying out a single ethics review?**

It is not a requirement that the sponsor indemnifies the HREC for the advice it provides when carrying out a single ethics review. The HREC must be assured of legal protection by the institution under which it has been established.

**2. What indemnity does the sponsor need to provide to an institution accepting the single ethics review outcome of the HREC?**

The sponsor does not need to provide indemnity to the accepting institution for using the advice received from the HREC to inform their decision about whether or not to participate in a multi-centre research study. The accepting institution will use their institutional processes (i.e. research governance and/or risk management practices) to make this decision.

**Note:** there may be other indemnities that a sponsor may wish to provide to an institution or a HREC that are outside the provision of a single ethics review. For example, a commercial sponsor of a clinical trial may be requested to provide indemnity to the HREC, the institution where it sits and all participating institutions for any injury to research participants that results from the use of the product (device or drug) under investigation.

## Further information

Further institutional-specific questions should be directed to your appropriate institutional research governance area, insurer or legal department.

Questions not included in this document may be sent to [ethics@nhmrc.gov.au](mailto:ethics@nhmrc.gov.au) ([link sends e-mail](#)).