

# Griffith University Research Ethics Manual

## Indemnity and Insurance

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## 1.0 Introduction

**Just as human research has the potential to generate great benefits, it can unfortunately cause significant harm. Such harms can result in claimable damages.**

As a component of our responsibility to participants in Griffith University research, it is important there is sufficient indemnity and insurance in place to cover these damages. In addition to safeguarding the rights of participants this is also important to protect those who undertake research.

As discussed in [Booklet 9 of this Manual](#), risks in human research are not limited to physical harms, but also include psychological, social, economic and legal harms. Consequently, human research across most disciplines requires sufficient insurance and indemnity cover.

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## 2.0 National guidelines

**The National Health and Medical Research Council (NHMRC) is the Australian body charged with the responsibility of issuing standards for the conduct of clinical research and has also issued standards for the operation of human research ethics committees.**

The international standard for clinical practice is [Integrated addendum](#) to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (R2) and the associated Australian standard is [Australian Clinical Trial Handbook](#) that incorporates *ISO 14155 Clinical Investigation of Medical Devices*.

Following the release of the *Day Report* (1993) the NHMRC released the *Report on Compensation, Insurance and Indemnity Arrangements for Institutional Ethics Committees* (now rescinded). The recommendations of these reports are reflected in sections 5.1.38 and 5.1.39 of the [National Statement on Ethical Conduct in Human Research](#) (2007, updated 2018). Section 5.1.38 of the [National Statement](#) directs that a human research ethics committee must be satisfied that the sponsor of trials have sufficient insurance and indemnity arrangements in place as required by ICH E6(R2) and ISO 14155. In addition to this requirement for clinical

research, s5.1.39 directs that “institutions must also have arrangements to compensate participants for harm resulting from negligence in research” (rather than just clinical trials).

Furthermore, [section 5.1.9 of the National Statement](#) stipulates that members of a human research ethics committee must receive a formal assurance of legal protection for liabilities that may arise in the course of their bona fide conduct of ethics review duties.

Based upon the above the University has established arrangements for the insurance/indemnification of approved research protocols and for the members of the University’s ethics committees.

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### 3.0 Standard insurance/indemnification arrangements

**In accordance with Australian requirements and international guidelines, the University provides indemnification to researchers and the members of the University’s research ethics review bodies on the basis of them being either:**

1. students, staff, voluntary worker, foundation, institute, centre or other body, affiliated to or operating within the framework of the University and formed by or with the knowledge and consent of the University; or
2. any person acting in an honorary (academic or otherwise) capacity for the University and includes honorary research fellows and voluntary workers who occupy a duly recognised position in the business of the University.

This indemnification covers activities that are officially approved and undertaken with the knowledge of the University or under the direction or control of, or at the request of, or which are activities relevant to that person’s position with the University.

In practice this means that the conduct of a protocol, appropriately approved by the relevant GUHREC expedited review processes and conducted in accordance with the University’s research ethics arrangements, is covered by this indemnification. Members of the GUHREC expedited review processes are also indemnified under this framework.

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### 4.0 Standard Clinical trials and special categories of research

**Previously, special indemnification and assurance arrangements applied to some categories of activities (such as clinical trials and high-risk research). In these cases, before authorisation to commence such an activity will be issued, the Research Ethics and Integrity team will liaise with the Manager, Insurance.**

Now the standard arrangements (see 3.0) apply to all research without researchers needing to consult the Manager, Insurance and Risk Management.

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### 5.0 Travel Insurance

The University's indemnification of research conducted under the auspices of the University provides travel insurance. However, Griffith University researchers who are traveling to conduct research activities are urged to consult the Travel insurance page (Insurance (griffith.edu.au)) and make contact with the Insurance office with any questions.

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## 6.0 Further information

All insurance enquiries should be directed to the Manager, Insurance; email: [insurance@griffith.edu.au](mailto:insurance@griffith.edu.au) or telephone (+61 7) 3735 7971.

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## Contacts

There are a number of resources available to assist researchers formulate an appropriate response to a question or challenge about the design and/or conduct of a project. This includes the Griffith University Research Ethics Manual and the Human Research Ethics Information Sheet Series. These documents are available from the URL below.

**Research students** – The first point of contact for research students for advice on any research ethics matter is always your supervisors.

**REAs** – All academic elements of the University have been asked to appoint at least one member of academic staff as a Research Ethics Advisor. REAs are a local contact for advice, information and suggestions. The contact details of all the current REAs can be found on the URL below.

**Office for Research** – Staff in the Office for Research (see below) are available to advise with the process of lodging an application or other administrative matters, procedural or policy questions. However, you will be asked what advice you have sought or received already (e.g. consultation with the REA for your area).

## Manager, Research Ethics and Integrity

Tel: (07) 373 54375  
[research.integrity@griffith.edu.au](mailto:research.integrity@griffith.edu.au)

## Policy Officer, Human Research Ethics and Integrity

Tel: (07) 373 58043

## Research Ethics Officer

Tel: (07) 373 52069

## Ethics Administration Officer

Tel: (07) 555 29253

On the ethics web site you will find:

<https://www.griffith.edu.au/research/research-services/research-ethics-integrity/human>

- The other booklets of the *Griffith University Research Ethics Manual*
- The *Griffith University Human Research Ethics Information Sheet Series*
- Either downloadable copies of, or links to, the various application forms
- Contact information for the Research Ethics Advisers (REA) and other contacts
- Educational and other resource material
- Useful external links



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