HUMAN RESEARCH PROJECTS INSURANCE GUIDE

Legal and Risk Branch
Division of University Operations
Tel: +61 8 8313 4539
Email: helpdesklegal@adelaide.edu.au
Human Research Projects Insurance webpage

CRICOS Provider Number 00123M

This guide has been designed to assist staff, students and titleholders of the University of Adelaide who are leading or participating in human research projects.

Included in this guide:

GENERAL INFORMATION

The University has a number of policies to protect research participants and University staff, students and titleholders who are leading or participating in human research projects.

In this guide, "**conducted by the University**" means managed, directed, run, in the control of, led by, supervised and carried out.

Conditions to cover

- Insurance is only available if the person/s providing medical treatment is qualified to perform the treatment and in the case of students participating that there is appropriate Supervision
- All human research projects must be ethics approved
- Insurance will not cover wilful misconduct or any deliberate breaches of confidentiality
- Insurance will not indemnify third parties and/or Sponsors

Policy Details

Clinical Trials Insurance
This policy covers the University (and any subsidiary company), its employees, students, contractors, medical practitioners, medical nurses and dentists, hospital or contract research organisations while engaged in the performance of work for the University (or any subsidiary company), for all sums they are legally liable to pay for loss in respect of a claim by a research participant arising from a human research project conducted by the University and covered by the policy.
The policy also provides no fault compensation for research subjects who suffer bodily injury in human research projects conducted by the University.

Public Liability Insurance
This policy covers the University (and any subsidiary or related party), cooperative research centres, its employees, students, honorary research fellows, visiting academics, volunteer workers and visiting academics for third party bodily injury and property damage caused by an event in connection with a human research project conducted by the University.

Medical Malpractice Insurance
This policy provides indemnity to the University in the event of a claim for loss, damage or injury by a person who has been provided with medical treatment or advice by a registered medical practitioner employed or engaged by the University during a human research project conducted by the University.

It is a condition of the University's policy that all registered medical practitioners must, at their own cost, maintain separate private medical indemnity insurance and be fully insured for their own malpractice, professional errors, omissions or negligence.

Professional Indemnity Insurance
This policy covers the University (and any subsidiary or related party), cooperative research centres, its employees, students, honorary research fellows, visiting academics, volunteer workers and visiting academics for third party bodily injury and property damage caused by the provision of negligent advice or a breach of duty owed in a professional capacity by a person employed or engaged by the University during a human research project conducted by the University and covered by the policy.

STEPS TO OBTAIN COVER

1. Obtain appropriate ethics approval

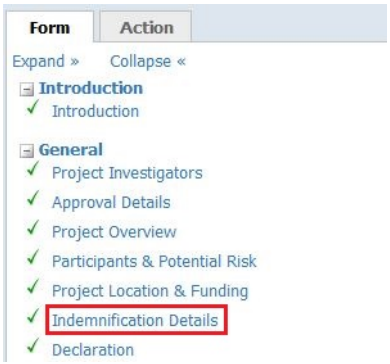
Researchers who are involved in a human research project must ensure that the project has been through the appropriate level of ethical review, and that ethics approval has been granted, before it can commence. All human research must be either approved by the University's HREC or an HREC approved by the University.

2. Notify the University of ethics approvals granted by other institutions

Researchers leading or participating in projects that have been approved by another institutional Human Research Ethics Committees (HREC) must notify the University's HREC of the project using the online notification eForm in the ResearchMaster system.

3. Request a Certificate of Insurance (if required)

Certificates of Insurance can be requested on the "Indemnification Details" page of the notification eForm. Once completed, the form will be workflowed to the Legal and Risk Branch for review. If a Certificate of Insurance has been requested, the relevant certificates will be emailed to the Investigators involved in the project on approval.



Please contact the HREC Secretariat for assistance with online notifications or refer to the support materials and guides.

4. Insurance Office notifies project to insurer

All projects that are reported to the University's HREC are notified to the University's insurers. This ensures that staff, titleholders, students and research participants are indemnified, or covered, by the University's insurance policies.

Failure to notify the University of any project will:

- result in a denial of compensation to a research participant who alleges a bodily injury as a result of participating in the trial or study.
- affect the indemnity provided to staff, titleholders or students under the policies.

AGREEMENTS WITH THIRD PARTIES

Contracts or agreements with third parties for the University to undertake clinical trials or human studies may contain clauses that compromise the University's insurance cover. All such agreements should be reviewed and approved at the local level. If there are any concerns, please send to helpdesklegal@adelaide.edu.au for legal review prior to commencement of the study.

REPORTING ADVERSE EVENTS AND CLAIMS

It is a condition of the University's insurance policies that the University report to its insurer any adverse event arising during a human research project. Notification of adverse events ensures that staff, titleholders, students and research participants are indemnified by the University's insurance policies.

The University's Clinical Trials, Medical Malpractice and Professional Indemnity policies start each year on 1 January and expire on 31 December (called the policy year). The policies are "claims made and notified policies" which means all adverse events must be notified to the University's HREC Secretariat as soon as they are known; and within the same policy year as the event itself.

The failure to notify adverse events to the University's HREC Secretariat will result in:

- a denial of any subsequent claim for compensation by a participant who alleges a bodily injury as a result of participating in the project or study;
- a denial of the indemnity provided to the University, its staff or students under the Clinical Trials, Medical Malpractice and/or Professional Indemnity policies; and
- the University and the staff or student being potentially exposed to a claim without any opportunity to benefit from an insurance policy;
- costs incurred to responsible area (i.e. Clinic, School or Faculty).

Researchers must immediately report the details of any adverse event arising as a result of a human research project to hrec@adelaide.edu.au and helpdesklegal@adelaide.edu.au using the report form on the next page.

REPORTING ADVERSE EVENTS

Please complete this form to report an adverse event. Email the completed form to the University's HREC Secretariat (hrec@adelaide.edu.au) and the Legal and Risk Branch (helpdesklegal@adelaide.edu.au).

PROJECT / STUDY / TRIAL NAME				
HREC APPROVAL *Please indicate the name of any Ethics Committees that have approved this project, and the relevant approval no.*				
PRINCIPAL INVESTIGATOR NAME				
DATE OF EVENT				
DATE EVENT REPORTED TO PRINCIPAL INVESTIGATOR				
PARTICIPANT DETAILS	**Name:**		**Study ID:**	
	D.O.B.:		☐ **Male** ☐ **Female**	
LOCATION OF EVENT *Eg. Hospital, clinic, private rooms*				
FACULTY/SCHOOL/BRANCH				
PRIMARY RESEARCH STAFF *add if more than one*	**Name:**			
	Title:			
	Email:		**Phone:**	
BACKGROUND / DESCRIPTION OF EVENT *What happened?*				
ENQUIRIES / INVESTIGATIONS UNDERTAKEN *What have you done about it?*				
CURRENT STATUS *How is the participant now? Has the trial been suspended / terminated?*				
ASSESSMENT OF RISK *Is the event associated with the project / study / trial?*				
DATE OF THIS REPORT				
PERSON MAKING THIS REPORT	**Name:**			
	Title:			

