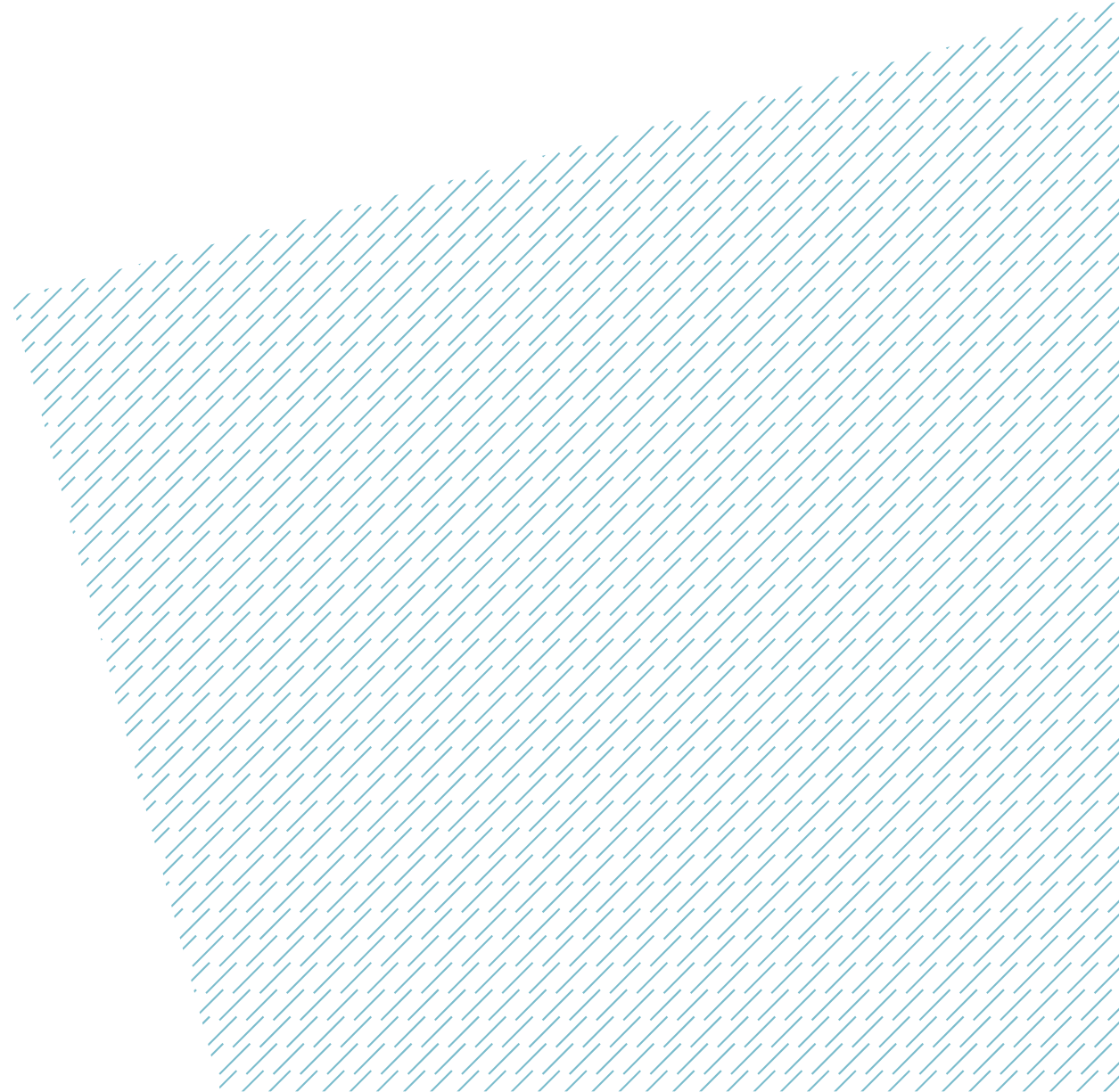




# Clinical Trials Insurance

July 2022





# Coverage

- Limit \$20m any one claim and in the aggregate
- Excess \$10k each and every claim
- Insurer/underwriter: Newline
- Broker: Willis Towers Watson (WTW)
- Territory: Worldwide (except where local laws prevent this)
- Two main coverage sections:
  - **No Fault Compensation:** no need to establish liability; compensation paid if research subject sustains a bodily injury arising from the clinical trial; governed by Compensation Conditions (in policy)
  - **Legal Liability:** operates like other liability policies; claimant must allege negligence and initiate legal proceedings with claim for damages



# Who is Insured?

- The University and its subsidiaries
- UoM directors, employees, students (past/present/future)
- Clinical Trial Contractors
- Contract Research Organisation
- Medical Person (AHPRA-reg'd medical practitioner, medical nurse, dentist) who provides advice to a CTC or CRO
- Ethics Committee (iro clinical trials covered by the policy)
- Data Safety Monitoring Board (iro clinical trials covered by the policy)



# Who is Insured?

## Clinical Trial Contractor

- *“A person/organisation engaged to provide service, advice or instruction in connection with a clinical trial within the scope of and in accordance with its applicable clinical trial protocol”*
- Intended to include honorary academics
- MDHS Legal is drafting an updated definition of “honorary academic” to fully capture all those performing this role across the University (not just iro clinical trials)

## Contract Research Organisation

- *“A person/organisation that provides professional services in connection with, or that organises or runs clinical trials within the scope of and in accordance with its applicable clinical trial protocol”*



# Notification triggers

All UoM clinical trials are automatically covered with no need to notify insurer, except:

- Trials specifically targeting **under 5s**
- Trials specifically targeting **pregnant women** or involving pregnancy studies
- Trials in any **foreign country**

To confirm: trials in the above categories can still be insured, they just need to be notified to the insurer first.

But note: certain trials are excluded.

If in doubt, discuss with OREI and/or UoM Insurance Office



# Foreign country trials

## Admitted/Non-admitted territories

- Insurance laws vary from country to country
- Some permit insurers to operate on a “non-admitted” basis, i.e. can insure activity in that country without being licensed by the insurance regulator in that country
- Others mandate insurers must be “admitted” to operate in that country, i.e. must be licensed by the country’s insurance regulator

## Process

- Notify UoM Insurance Office (direct or via OREI) >> Broker >> Insurer
- Insurer determines admitted/non-admitted status for that country
  1. Can be non-admitted: trial can be covered under UoM policy; no extra cost
  2. Must be admitted: trial needs a “local policy”; additional premium charged in local currency
    - UoM broker can arrange this local policy
    - Local CRO can often also arrange this local policy



# Foreign country trials

## Example

- Trial proposed for Canada
- Notified to UoM Insurance Office >> Broker >> Insurer
- Canada is admitted-only territory: local policy in Canada required
- UoM's insurer can provide local Canadian policy through their Canadian subsidiary, with UoM policy sitting above local Canadian policy
- Local policy quote:
  - C\$5m limit
  - C\$5,000 premium, plus local taxes
  - Covering up to 50 trial participants
  - Requires details of Canadian client/CRO
  - Requires details of a Canadian broker (UoM broker can assist with this, or local CRO could provide)



# Key exclusions

- Failure to follow or comply with the terms of the clinical trial protocol
  - Note: such incidents may be covered under UoM's medical malpractice or professional indemnity insurance
- Failure to get written informed consent of each trial participant
- TSE/CJD trials
- HIV/AIDS trials



# Further Information

- KBA: Clinical Trials and Medical Malpractice Insurance  
Knowledge Base - Staff Services ([service-now.com](http://service-now.com))
- KBA has link to Certificate of Currency
  - provides evidence of UoM's insurance
  - can be supplied to anyone who would like evidence of UoM's insurance
- Insurance Office – [ash.hepburn@unimelb.edu.au](mailto:ash.hepburn@unimelb.edu.au)
- OREI