Clinical Trials Protection

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Unimutual defines a clinical trial as:

- Any human trial or health volunteer study which complies with the statutory requirements or guidelines of the relevant authority, department or public or registered private body in the country in which the trial or study takes place; or

- A study that has to be approved by the Members Human Ethical Committee.

However, the following are **EXCLUDED** unless specifically agreed by us:

- any trial involving pregnant women, breastfeeding women and infant breast-fed by the trial participants,
- Any trials taking place in the USA or Canada
- Any COVID-19 related trials.

If you require special acceptance for an excluded Clinical Trial, please email service@unimutual.com.au and include the following documents:

- Clinical Trial Protocol Information
- Patient Information Sheet

The information will be reviewed and either additional information requested, or acceptance confirmed.

WHO IS PROTECTED:

The following are deemed Protected Persons:

- Employees
- Voluntary workers
- Students
- Sub-contractor
- Doctor
- Consultant
- Physician
- Hospital or contract research organisation
- Nurse performing work on behalf of the Member
- Senate, Council, Committee, Ethics Committee
- Board members

but only in respect of a clinical trial undertaken by the member or an affiliate (as the case may be) and only whilst acting within the scope of their duties in connection with such clinical trial

WHAT IS PROTECTED:

Legal Liability

- The compensation that you are liable to pay a third party
- Your defence costs (including fees or disbursements to the independent lawyer).
- Your enquiry costs

Both Legal Liability and No Fault Compensation are protected.

"No fault" means the research subject does not need to take legal action to receive compensation, where both parties agree that the trial caused bodily injury (refer to the wording for full details relating to conditions of compensation).

WHAT IS NOT PROTECTED:

Apart from those trials which require specific disclosure for Protection to be considered and granted exclusions also apply to the following (refer to the wording for full details).

- Any condition in any way connected with HIV or AIDs
- Circumstances occurring prior to 1997
- Claim resulting from a clinical trial that commenced prior to the retroactive date, where one is specified in the Schedule.
- Failure of a drug, device or procedure the subject of clinical trial to perform its intended purpose or function
- Clinical Trials not approved by a Human Ethics Committee
- Health care professionals, unless previously agreed

WHICH CLINICAL TRIALS NEED TO BE DECLARED AT RENEWAL:

The following are required to be included in the listing of Clinical Trials:

- Any clinical trial specifically accepted for inclusion after referral.
- all CTN and CTA trials which are current or completed during the Protection Period or due to commence in the next Protection Period.
- all trials that are a multi-Centre trial/study;
- any trial/study where you are collaborating with any other Australian University or Research Institute.
- any trial/study where you are the Sponsor and involving any other Australian University or Research Institute, or the Sponsor is another Australian University or Research Institute.

CTN/CTA trials mean as per the TGA definition below.

- Clinical trials conducted using “unapproved therapeutic goods” in Australia, that is, goods which have not been evaluated by the TGA for quality, safety and efficacy and entered into the Australian Register of Therapeutic Goods (ARTG) for general marketing, are required to make use of the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes.’

- The definition of an unapproved good can encompass many aspects of a product. These include formulation, dose form, name, indications, directions for use and container. Hence simply because a product is entered into the ARTG, this may not necessarily mean that the product intended for use in a clinical trial does not need an exemption via the CTN or CTA schemes in order to be lawfully supplied. The indication may be quite different, or dosage higher than that approved for marketing, or the product may be sourced from a foreign market, for example, this may include consultation hours with experts to support the C-suite pre-crisis and during crisis.

OVERSEAS CLINICAL TRIALS

Whilst the Clinical Trials Protections offers cover worldwide excluding USA and Canada, if you are undertaking a Clinical Trial in an overseas country, that country may have a requirement for a local policy with a local insurer to be affected.

You will need to seek your own legal advice on this matter. It is your responsibility to understand all the laws and rules of the country in which you are going to conduct the trial.

Note that if a local policy is taken out, the Unimutual Protections will sit as additional cover in excess of the local policy.

GENERAL INFORMATION

Clinical trials of medicines and medical devices conducted in Australia are subject to Commonwealth Government regulation administered by the Therapeutic Goods Administration (TGA). Refer to the website TGA for full details:

This summary is provided for informational purposes only and contains general advice that is given without considering Member’s objectives, financial situation or needs. Please consider the appropriateness of the information and any general advice provided considering your objectives, financial situation or needs. Please read the Product Disclosure Statement (PDS) to reference the exact protection terms and conditions, and before acting on the advice offered, please seek separate professional legal or financial advice. The content mentioned in this fact sheet does not constitute professional advice, and you accept and agree that following any information or recommendations provided herein is at your risk.

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