



Unimutual Limited  
ABN 45 106 564 372  
AFS Licence No 241142

## **What constitutes a Clinical Trial for the purpose of Unimutual protections?**

1. Is the study or research to test:

- a drug; **or**
- a surgical procedure or device; **or**
- a therapeutic procedure or device; **or**
- a preventative procedure or device; **or**
- a diagnostic procedure or device;

where the nature of the study or research is such that it requires the investigator or an assistant to be a registered medical practitioner or other registered qualified health service provider?

2. Does the study or research require any:

- penetration of the skin (other than taking of blood samples); **or**
- biopsy or any taking of or extraction of tissue samples; **or**
- penetration of the bodily orifices (other than ears or mouth); **or**
- insertion of diagnostic or other device within the bodily orifices (other than ears or mouth);

to be undertaken by a registered medical practitioner or other registered qualified health service provider?

If the answer is “Yes” to **either** 1 or 2 above, the study or research is a clinical trial for the purpose of Unimutual’s protections.

However, please note that if the study or research:

- involves evaluating outcomes of established health care management or treatment relating to the condition or illness from which the participants are suffering; **or**
- only involves the participants completing questionnaires or interviews;

then the study/research is not a clinical trial for the purpose of Unimutual protections.