



NO FAULT COMPENSATION INSURANCE FOR CLINICAL TRIALS AND/OR HUMAN VOLUNTEERS STUDIES

Clinical Trial Presentation 2025

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A business of Marsh McLennan



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Agenda

POLICY DETAILS

- **The Insurer:** Newline Underwriting Management
- **Market:** London
- **The period of insurance:** 1 January 2025 till 31 December 2025
- **The limit of indemnity:** USD 5,000,000
- **Deductible:** USD 5000 each and every claim

COVER

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The Underwriters will indemnify the **Stellenbosch University** (SU) against all sums, that they shall become liable to pay as damages or compensation and claimants' costs and expenses in respect of any claim **made by Research Subjects** for **Bodily Injury** caused by an Occurrence within the Policy Territory and arising out of the Trial(s) of the Insured as stated in the Schedule.

Provided that:

- The claim is first made in writing to SU during and within 30 days of the expiry of the indemnity period
- All bodily injuries that resulted from one Trial will be considered as one Occurrence
- The Underwriters will also pay Legal Costs in addition to the Limits of Indemnity

DEFINITIONS

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BODILY INJURY

Accidental physical injury, sickness, disease or death and shall include, but not by way of limitation mental injury, mental anguish, shock, false arrest or invasion of the right of privacy

INSURED

- Shall mean **SU** and at the written request, shall also include:

(a) Any **director or business partner** of SU, but only whilst acting in their respective capacities for SU

(b) Any **Person Employed**, including Medical Persons, but only whilst **acting within the scope of their duties for SU**

(c) Any **sub-contractor, doctor, consultant, physician, hospital or contract research organisation or nurse** who will be performing work for SU in respect of a Trial covered by this policy

d) Any **Ethics Committee or its members** that has approved a Trial

DEFINITION

RESEARCH SUBJECT

- Shall mean any person participating in a Trial including their dependants, heirs, executors' administrators and legal representatives

TRIAL

- shall mean any Clinical Trial or Healthy Volunteer Study which complies with the statutory requirements or guidelines of the relevant person authority department or public or private body in the country in which the Trial occurred.

MEDICAL PERSONS

- shall mean Licensed Physicians, Doctors, Medical Nurses and Dentists

EXTENSIONS

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EXTENSIONS

- **BREACH OF CONFIDENTIALITY EXTENSION**

The Underwriters shall indemnify the Insured against legal liability for damages and claimants' costs and expenses in respect of **an unintentional breach** of confidentiality committed in connection with a Trial, provided that the Claim in respect of such liability is first made against the Insured during the Period of Insurance and is notified to the Underwriters during the Period of Insurance

- **MANSLAUGHTER DEFENCE COSTS (ETHICS COMMITTEE)**

The Underwriters will indemnify the Ethics Committee or any member thereof in respect of legal costs and expenses incurred with the **Underwriters written consent** in the defense of any **criminal proceedings brought** (or in an appeal against conviction arising from such proceedings) **as a result of manslaughter** arising from any event which may be the subject of indemnity under this Policy

Provided that:

- the proceedings relate to an offence alleged to have been committed during the Period of Insurance and in the course of the Business

EXCEPTIONS

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- The Underwriters shall not be liable to indemnify the Insured against
 - any Trial performed **without the informed written consent of each Research Subject** obtained prior to the participation of such Research Subject in such Trial.
 - any Claim arising from Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named
 - any Claim arising from any condition directly or indirectly caused by or associated with Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).

QUESTIONS

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What are the different insurances and who/what is covered?

- **No Fault policy** covers SU in the event that they are held liable by a trial participant.
- **Professional Indemnity (PI)** policy will cover SU in the event that they are legally liable to pay, arising out of breach of **professional duty** by reason of any neglect, error or omission by any individuals acting on behalf of SU.

Does SU staff need any other insurance?

If acting on behalf of SU, they will be covered by the PI policy

Are non-employee contracted to SU covered?

Yes, as long as they are acting on behalf of SU

QUESTIONS

Does the insurance cover the Participant in the event of a Breach of Confidentiality?

No, it does not cover the participant, but it covers SU if they are held liable by the participant

Do we have liability cover if a participant slips at a site?

Yes, if the property belongs to SU, the Public Liability policy will respond.

Does the insurance cover a participant in our vehicles?

No, that should go to the RAF, but you can arrange Personal Accident cover for participants that you transport

Thank you