NEWLINE GROUP®

Clinical Trials No Fault Compensation Proposal

IMPORTANT NOTICE (This notice must be read prior to completing this proposal)

Your Duty of Disclosure

Before you enter into a contact of insurance with the Underwriters you have a duty, under the Insurance Contracts Act 1984, to disclose to the Underwriters every matter that is known to you or you could reasonably be expected to know to be a matter relevant to the Underwriters' decision of whether to accept the risk and, if so, on what terms.

You have the same duty to disclose those matters to the Underwriters before you renew, extend, vary or reinstate a contract of insurance.

Your duty does, however, not require disclosure of a matter:

- that diminishes the risk to be underwritten by the Underwriters;
- that is common knowledge;
- that the Underwriters know or, in the ordinary course of business as an Underwriter, ought to know; or
- as to which compliance with the duty is waived by the Underwriters.

The requirement of full and frank disclosure of anything which may be material to the risk for which you seek cover (for example, claims, whether founded or unfounded), is of the utmost importance with this type of insurance.

If you do not understand any part of this Proposal Form you should seek advice from your insurance broker/professional insurance adviser, as you will be bound by your answers and any information you provide.

Non-Disclosure

If you fail to comply with your duty of disclosure, the Underwriters may be entitled to reduce its liability under the contract of insurance in respect of a claim. If your non-disclosure is fraudulent, the Underwriters may also have the option of avoiding the contract from its beginning.

Claims Made & Notified Insurance

This insurance is written on a "claims made and notified" basis. This means that the insurer indemnifies you for Claims (as defined) that are made against you during the period of insurance and notified to the Insurer during the period of insurance. The policy does not provide cover for any claims made against you during the period of insurance if at any time prior to commencement of the period of insurance you became aware of facts which might give rise to those Claims being made against you, or for any claims made against you arising from any Occurrence happening prior to the Retroactive Date.

Section 40(3) of the Insurance Contracts Act 1984 provides that where you gave notice in writing to the insurer of any facts that might give rise to a Claim against you as soon as reasonably practical after you become aware of those facts, but before the expiry of the period of insurance, the insurer cannot refuse to pay a Claim which arises out of those facts, when made, because it was made after the period of insurance had expired.

Subrogation

In the event you prejudice the Underwriters' rights to recover a loss from another party, this may exclude or limit the Underwriters' liability in respect of that loss.

Change in Risk or Circumstances

You should advise the Underwriters as soon as practicable of any material change in your business activities (as disclosed in the Proposal Form).

Privacy

New privacy legislation took effect on 21 December 2001. The legislation regulates the way private sector organisations can collect, use, keep, secure and disclose personal information. We have developed a Privacy Policy that explains what sort or personal information we hold about you and what we do with that information. Please refer to our website for a copy of our Privacy Policy; http://www.newlinegroup.com.au/privacy-policy.htm

IF MORE SPACE IS REQUIRED TO ANSWER A QUESTION COMPLETELY, PLEASE COMPLETE ON A SEPARATE PAGE AND SUBMIT WITH THIS PROPOSAL FORM.

Newline Australia Insurance Pty Ltd ABN 81 118 089 651
Level 31, 570 Bourke Street, Melbourne, VIC 3000
PO Box 16208, Collins Street West, VIC 8007
Tel: 03 9999 1906 Fax: 03 9670 0045
Email: quote@newlinegroup.com.au

Please check the appropriate box.

Application is for: ☐ New Business ☐ Renewal

Full Name(s) of all companies or parties to be insured:

Address of Registered Office:

Full Description of Business:

Date Established:

Date First Commenced Conducting Clinical Trials:

1. Are all trials conducted in full accordance with:
   - a) National Health and Medical Research Council (NHMRC) guidelines requirements with protocols approved by a constituted independent Ethics Committee? ☐ YES ☐ NO
   - b) Royal Australian College of Physicians recommendations? ☐ YES ☐ NO
   - c) Applicable Government Department, Medical Body Pharmaceutical Industry Body Guidelines including Medicines Australia? ☐ YES ☐ NO
   - d) Department of Health and Ageing Therapeutic Goods Administration 'The Australian Clinical Trial Handbook' on Good Clinical Practice (GCP)? ☐ YES ☐ NO
   - e) I.C.H. Guidelines? ☐ YES ☐ NO
   - f) Do all First-In-Human studies follow the 2006 Guidelines to improve conduct of early stage clinical trials? ☐ YES ☐ NO
2. Provide the details of any incidents during the last 5 years that resulted in any Serious Adverse Event (SAE),Serious Adverse Drug Reaction (SADR) to patients or volunteers, and any other circumstances which might or have given rise to a claim of compensation against you:

PLEASE NOTE THE FOLLOWING IMPORTANT INFORMATION:

When completing and providing information in relation to your Clinical Trials the following definitions are intended:

Contract Research Organisation (CRO) - Management of the services delegated to them by sponsor companies and principal investigators

Human Research Ethics Committees (HRECs). Involvement as HREC

Independent Reviewer

Observational only

Local sponsor

Principal Investigator(s) in terms of GCP and TGA regulatory requirements. Includes members of the hospital or research site staff who conduct the trials and co-ordinate administrative and clinical work associated with the research

Sponsor - responsible for the CT design, initiation, management, protocol development and review. Endorses the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes

Staff assisting with Principal Investigation

Trial Host -Research facilities being used to host trial only

For each Clinical Trial please attached a copy of the following documentation:

(a) Protocol

(b) Volunteer Consent Form (if applicable)

(c) Any agreement/contract with other parties (if applicable)

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3. **PLANNED CLINICAL TRIALS**

Expected Commencement Date	(Est) Completion Date	Insured's Involvement In Trial	Study Protocol Title	Phase	First-In-Human Trial? If YES, please attach details of pre-clinical testing results	No. of subjects	No. of sites	Is the clinical trial conducted in Australia? If Yes, which State(s)? If No, which Countries?	Details of any additional Insured parties required to be covered by this Policy	Provide details of any other Insurance that provides cover for this Clinical Trial

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4. **ONGOING CLINICAL TRIALS**

Expected Commencement Date	(Est) Completion Date	Insured's Involvement In Trial	Study Protocol Title	Phase	First-In-Human Trial? If YES, please attach details of pre-clinical testing results	No. of subjects	No. of sites	Is the clinical trial conducted in Australia? If Yes, which State(s)? If No, which Countries?	Details of any additional Insured parties required to be covered by this Policy	Provide details of any other Insurance that provides cover for this Clinical Trial

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5. **COMPLETED CLINICAL TRIALS**

Expected Commencement Date	Completion Date	Insured's Involvement In Trial	Study Protocol Title	Phase	First-In-Human Trial? If YES, please attach details of pre-clinical testing results	No. of subjects	No. of sites	Is the clinical trial conducted in Australia? If Yes, which State(s)? If No, which Countries?	Details of any additional Insured parties required to be covered by this Policy	Provide details of any other Insurance that provides cover for this Clinical Trial

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6. **STAFF INVOLVEMENT IN THIRD PARTY CLINICAL TRIALS**

Expected Commencement Date	Completion Date	Insured's Involvement In Trial	Study Protocol Title	Phase	First-In-Human Trial? If YES, please attach details of pre-clinical testing results	No. of subjects	No. of sites	Is the clinical trial conducted in Australia? If Yes, which State(s)? If No, which Countries?	Are your Employees covered under any other Insurance that provides cover for this Clinical Trial? Please provide details.

7. In respect of Specified Trials is cover required in respect of Extended Discovery Period beyond the dates stipulated in the Trial Protocol? ☐ YES ☐ NO
If Yes, please provide details including the number of years.

8. a) Who are your current Insurer(s)?
If currently uninsured, please state.

b) What is the renewal deate of your current Insurance policy covering Clinical Trials?

c) If placed on a Claims Made basis, what retroactive date is currently applied to the policy?

d) Please tick the Limit(s) of Indemnity for which a quotation is required or local currency equivalent.

☐ AUD$ 5,000,000
☐ AUD$ 10,000,000
☐ AUD$ 20,000,000

I/ we declare that to the best of my/our knowledge and belief, the above statements are true and complete and will form part of the contract between me/us and the Underwriters.

Name:

Position:

Date:

Signature:

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