

Clinical Trials No Fault Compensation Proposal

IMPORTANT:

The form must be signed by a Partner or Director or Authorised Signatory of the Firm.

All questions must be answered. However, if a question or section is not applicable then please answer "N/A". The completion and signature of this form does not bind the Proposer or Underwriter to complete a contract of insurance unless specific agreement is given by both parties.

It is your duty to disclose all material facts to the Insurers. A material fact is one that is likely to influence a prudent Insurer's judgement and acceptance of your proposal. If you are in any doubt as to whether or not certain information is material then it should be disclosed.

If you have insufficient space to complete any of your answers please continue on your headed paper and attach it to this form.

If you have any queries then please contact either your authorised broker or us to discuss.

Newline Australia Insurance Pty Ltd

Craig Rowsell

Ph 03 9999 1908 / 0428 998 229

Email: crowsell@newlinegroup.com.au

Newline Australia Insurance Pty Ltd ABN 81 118 089 651

Level 31, 570 Bourke Street, Melbourne, VIC 3000

PO Box 16208, Collins St West, VIC 8007

Tel: 03 9999 1906 Fax: 03 9670 0045

Email: info@newlinegroup.com.au

Full Name (s) of all companies or Bodies to be Insured:

Address of Registered Office:

Full Description of Business:

Date Established:

Date first commenced conducting Clinical Trials:

For each trial to be insured please attached a copy Protocol Document (if Final version not available please submit Draft or Synopsis for quote) plus Informed Patient Consent Form

1.	Are all trials conducted in full accordance with:	
	a) National Health and Medical Research Council (NHMRC) requirements with protocols approved by an independent Ethics Committee?	YES <input type="checkbox"/> NO <input type="checkbox"/>
	b) Royal Australian College of Physicians recommendations:	YES <input type="checkbox"/> NO <input type="checkbox"/>
	c) Applicable Government Department, Medical Body Pharmaceutical Industry Body Guidelines including Medicines Australia?	YES <input type="checkbox"/> NO <input type="checkbox"/>
	d) Department of Health and Ageing Therapeutic Goods Administration 'The Australian Clinical Trial Handbook' on Good Clinical Practice (GCP)?	YES <input type="checkbox"/> NO <input type="checkbox"/>
	e) I.C.H. Guidelines?	YES <input type="checkbox"/> NO <input type="checkbox"/>
	f) Do all First-in-human studies follow the 2006 Guidelines to improve conduct of early stage clinical trials?	YES <input type="checkbox"/> NO <input type="checkbox"/>

2.	Are you the Sponsors of the Trial(s) to be Insured? If 'NO' please advise your involvement (ie Legal Representative, Local Sponsor, Clinical Research Organisation, Principal Investigator etc...)	YES <input type="checkbox"/> NO <input type="checkbox"/>
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3.	Are all trials conducted in Australia? If 'YES' are trials to be conducted in Victoria subject to VMIA requirements? If 'NO' then please state Territories under Q7	YES <input type="checkbox"/> NO <input type="checkbox"/>
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4. Give details of any Claims or Letters, Writs, Demands or Requests for Compensation received during the last 5 years which might give rise to a claim of compensation against you:

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5. DETAILS OF TRIALS **PERFORMED** IN THE LAST 12 MONTHS (please complete on separate page if insufficient room)
If any trials are First-in-Human then please state 'FIH' under Phase

Date Commenced	Date Completed	Study Title in Full	Phase	No of Subjects		Territory if not AUS
				Estimated	Enrolled to date	

6. SUMMARY OF TRIALS **PLANNED** FOR THE NEXT 12 MONTHS (please complete on separate page if insufficient room)
If any trials are First-in-Human then please state 'FIH' under Phase

Date Commenced	Date Completed	Study Title in Full	Phase	No of Subjects	Territory if not AUS

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<p>7. a) Who are your current Insurer(s)? If currently uninsured please state.</p> <p>b) What is the renewal date of your current Insurance policy covering Clinical Trials?</p> <p>c) If placed on a Claims Made basis what retroactive date is currently applied to the policy?</p> <p>d) Please tick the Limit(s) of Indemnity for which a quotation is required or local currency equivalent</p>	<p><input type="checkbox"/> AUD\$ 2,000,000</p> <p><input type="checkbox"/> AUD\$ 5,000,000</p> <p><input type="checkbox"/> AUD\$ 10,000,000</p> <p><input type="checkbox"/> AUD\$ 20,000,000</p>
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I / We declare that to the best of my/our knowledge and belief the above statement are true and complete and will form part of the contract between me/us and the Underwriters.

Name: _____

Position: _____

Date: _____

Signature: _____