

Proposal Form

Clinical Research Organisation

Public & Products Liability Insurance

Arranged through ASR Underwriting Agencies Pty Ltd Underwritten by Certain Underwriters at Lloyd's



IMPORTANT NOTES

PLEASE READ THESE GUIDANCE NOTES BEFORE COMPLETING THE PROPOSAL FORM. WHERE FURTHER INFORMATION IS REQUIRED PLEASE ATTACH IT TO THIS PROPOSAL FORM.

This proposal must be typed, or completed in ink and signed and dated by such person (Proposer/You/Your) who must be of legal capacity and authorised by the Proposer to seek a quotation for Liability Insurance and any additional coverage that may be provided by the Insurer. Please answer every question fully, and state "NIL" or "NONE" as applicable. Incomplete answers may not be accepted and can delay quotation.

Should there be insufficient room in the Proposal Form for full details, please attach further information on signed and dated sheets, wherever possible following the same format and paragraph number.

It is the duty of the Proposer to disclose all material facts to Insurers. Where this is omitted, the Insurers may avoid their obligation under the Policy.

For the purpose of the Proposal and for all purposes relating to any policy issued pursuant to this Proposal, a 'material fact' shall be deemed to be one that would be likely to influence an Insurer's judgement and acceptance of Your Proposal.

Upon acceptance of the Insurers' terms and conditions and payment of the premium, all information provided by the Proposer together with the guidance notes will be deemed to be incorporated in the contract between Insurers and the Proposer.

Your Duty of Disclosure

Before You enter into an insurance policy, it is Your duty to disclose every matter that You know, or could reasonably be expected to know, to be relevant to the Insurer's decision whether to give You insurance cover and, if so, on what terms.

Consequences of Non-Disclosure or Misrepresentation

If You breach Your duty of disclosure; the Insurer(s) may be able to refuse to pay a claim or to cancel Your policy. The same applies where You have made a misrepresentation, if fraudulent (ie. done deliberately for the purpose of obtaining insurance, or for obtaining it on favourable terms) the Insurer(s) may be able to 'avoid' Your policy. This means that the Insurer(s) can treat the policy as never having existed. Non-disclosure or misrepresentation in relation to one policy may affect Your ability to obtain other insurance in the future.

If You are unsure whether some information may be disclosable or not we suggest You call Your insurance broker and seek guidance.

Privacy

We are committed to protecting Your privacy. We only use the personal information You provide to us to quote on and insure this risk. We only provide Your personal information to our Insurer(s) and Reinsurers (and their representatives) and those we appoint to assist us with claims under Your policy (ies). We do not trade, rent or sell Your information. Some or all of the Insurer(s) and Reinsurers may be overseas.

If You don't provide us with complete information, we cannot properly quote for Your insurance and we cannot insure You. You can check the information we hold about You at any time. For more information about our Privacy Policy, ask us for a copy. Copies of the Proposal Form should be retained for Your own records.

Excess

The policy provides that You will be required to bear a specified amount of all claims and this is for each and every claim made against You including defence costs. We will let You know when the excess is payable.

Your Legal Liability

If you take out a Liability cover section, the financial risk of court awards through litigation is ever increasing and we recommend that You select a Limit of Liability that takes into account the future cost of claims including legal fees and costs of defence. Even higher limits are available than your current limit if required. Defence costs are included within the limit of liability, when you take out a Liability cover section.

Waiver of Rights

If You have entered into an agreement with another party, which prevents your Insurer from taking recovery action for compensation from that party it may affect Your rights to cover under this Policy. Should You now be a party to such an agreement or be requested to enter such an agreement in the future, please advise your Broker in writing so we may notify the Insurer.

Broker

Contact Name

Phone

Fax

Email

Company Information

Full Name of Insured(s)

ABN

Address of Registered Office

Full Business Description

Website Address

On what date was the Company first established / commenced trading

Is your company involved in Clinical Trials? yes no

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

Operational Information

- 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 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. Are you the Sponsors of the Trial(s) to be Insured?** yes no
If 'NO' please advise your involvement (ie Legal Representative, Local Sponsor, Clinical Research Organisation, Principal Investigator etc.)

- 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 no

- 4. Please provide 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.**

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

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	Completed Date	Study Title in Full	Phase	No of Subjects	Territory if not AUS
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- 7.
- a) Who are your current Insurer(s)? *If currently uninsured please state.*
- b) What is the renewal date 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 state Limit(s) of Indemnity for which a quotation is required or local currency equivalent

Additional Information

Declaration of Your Duty of Disclosure

I confirm that:

I am authorised on behalf of the insured(s) to sign this proposal.

I understand that the duty of disclosure applies to all insured(s). The answers are provided on behalf of all persons/entities comprising the insured(s).

I understand the questions in the proposal.

Whilst some or all of the answers to the questions may not be checked by me I certify they are correct to the best of my knowledge and belief.

Do you consider that your establishment is a good insurance risk? yes no

AUTHORISED SIGNATORY

Dated

NAME OF SIGNATORY

Position