

Sponsor's/Legal Representative/ Clinical Research Organisations Questionnaire

AUSTRALIAN CLINICAL TRIALS NO FAULT COMPENSATION

(please note that where No Fault Compensation is not acceptable more specific local cover can be arranged but a different proposal form may be required. In this instance please contact either your authorised broker or us to discuss)

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 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.

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QUESTIONS	ANSWERS
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	

<p>1. Are all trials conducted in full accordance with:</p> <table style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="width: 60%; padding-left: 20px;">a) National Health and Medical Research Council (NHMRC) requirements with protocols approved by an independent Ethics Committee?</td> <td style="width: 40%; text-align: center;">YES / NO</td> </tr> <tr> <td style="padding-left: 20px;">b) Royal Australian College of Physicians recommendations:</td> <td style="text-align: center;">YES / NO</td> </tr> <tr> <td style="padding-left: 20px;">c) Applicable Government Department, Medical Body Pharmaceutical Industry Body Guidelines including Medicines Australia?</td> <td style="text-align: center;">YES / NO</td> </tr> <tr> <td style="padding-left: 20px;">d) Department of Health and Ageing Therapeutic Goods Administration 'The Australian Clinical Trial Handbook' on Good Clinical Practice (GCP)?</td> <td style="text-align: center;">YES / NO</td> </tr> <tr> <td style="padding-left: 20px;">e) I.C.H. Guidelines?</td> <td style="text-align: center;">YES / NO</td> </tr> <tr> <td style="padding-left: 20px;">f) Do all First-in-human studies follow the 2006 Guidelines to improve conduct of early stage clinical trials?</td> <td style="text-align: center;">YES / NO</td> </tr> </tbody> </table>	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	
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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												

<p>2. Are you the Sponsors of the Trial(s) to be Insured?</p> <p>If 'NO' please advise your involvement (ie Legal Representative, Local Sponsor, Clinical Research Organisation, Principal Investigator etc...)</p>	<p>YES / NO</p>
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<p>3. Are all trials conducted in Australia? If 'YES' are trials to be conducted in Victoria subject to VMIA requirements?</p> <p>If 'NO' then please state Territories under Q7</p>	<p>YES / NO</p>
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<p>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:</p>

<p>5. DETAILS OF TRIALS PERFORMED IN THE LAST 12 MONTHS (please complete on separate page if insufficient room)</p> <p>If any trials are First-in-Human then please state 'FIH' under Phase</p>
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Date Commenced	Date Completed	Study Title in Full	Phase	No of Subjects		Territory if not AUS
				Estimated	Enrolled to date	

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

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

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Date Commenced	Date Completed	Study Title in Full	Phase	No of Subjects	Territory if not AUS
Cont'd/.....					

<p>7.</p> <p>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 state Limit(s) of Indemnity for which a quotation is required or local currency equivalent</p>	<p>A\$.....</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.

<p>Name and position of person completing this Questionnaire:-</p>	<p>Name:</p> <p>Position:</p> <p>Signed:</p> <p>Date:</p>
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