SURA TECHNOLOGY RISKS

Level 14 / 141 Walker St
North Sydney NSW 2060
PO Box 1813
North Sydney NSW 2059

Clinical Trials Proposal Form

Telephone: 02 9030 9500
Web: www.sura.com.au

Clinical Trials Proposal Form

Important Information

In this application:

You / Your refers to all firms to be insured under this arrangement, including any predecessor or previous business for which cover is required.

Firm means any business, whether a sole trader, partnership or company, limited in liability or otherwise.

Principal means any Director, Partner, Member or Sole Trader.

The information You provide in this document and through any other documentation, either directly or through Your insurance broker, will be relied upon by the Insurer to decide whether or not to accept Your insurance as proposed and if so, on what terms.

Every question must be answered fully, truthfully and accurately. If space is insufficient for Your answer, please use additional sheets, sign and date each one and attach them to this document.

If You do not understand or if You have any questions regarding any matter in this document, including the Important Information, please contact Us or Your insurance broker before signing the Declaration at the end of this document.

Unless We have confirmed in writing that temporary cover has been arranged, no insurance is in force until the risk proposed has been accepted in writing by Us and You have paid or agreed to pay the premium.

Duty Of Disclosure

This Policy is subject to the Insurance Contracts Act 1984 (Act). Under that Act You have a Duty of Disclosure.

Before You take out insurance with Us, You have a duty to tell Us of everything that You know, or could reasonably be expected to know, may affect Our decision to insure You and on what terms. If You are not sure whether something is relevant You should inform Us anyway.

You have the same duty to inform Us of those matters before You renew, extend, vary, or reinstate Your contract of insurance. The duty applies until the Policy is entered into, or where relevant, renewed, extended, varied or reinstated (Relevant Time). If anything changes between when the answers are provided to Us or disclosures are made and the Relevant Time, You need to tell Us.

Your duty however does not require disclosure of matters that:

- reduce the risk;
- are common knowledge;
- We know or, in the ordinary course of Our business, ought to know; or
- We have indicated We do not want to know.

If You do not comply with Your duty of disclosure, We may be entitled to:

- reduce Our liability for any claim;
- cancel the contract;
- refuse to pay the claim; or
- avoid the contract from its beginning, if Your non-disclosure was fraudulent.

Claims Made Policy

Section 2 – Clinical Trials Liability and Section 3 – Third Party Cyber Liability are issued on a "claims made" basis. This proposal is for a Claims Made Policy. This means that the policy only responds to:

- claims first made against You and notified to the Insurer during the policy period arising from events after any retroactive date on the policy, and
- events of which You first become aware during the policy period that could give rise to a future claim provided that You notify the Insurer during the policy period of the circumstances of such events and they arose after any retroactive date on the policy.

When the policy expires, no claims can be made on the policy even though the event giving rise to the claim may have occurred during the policy period.

Privacy Statement

We are committed to protecting Your privacy in accordance with the Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs), which will ensure the privacy and security of Your personal information.

The information provided in this document and any other documents provided to Us will be dealt with in accordance with Our Privacy Policy. By executing this document You consent to collection, use and disclosure of Your personal information in accordance with Our Privacy Policy. If You do not provide the personal information requested or consent to its use and disclosure in accordance with Our Privacy Policy, Your application for insurance may not be accepted, We may not be able to administer Your services/products, or You may be in breach of Your duty of disclosure.

Our Privacy Policy explains how We collect, use, disclose and handle Your personal information including transfer overseas and provision to necessary third parties as well as Your rights to access and correct Your personal information and make a complaint for any breach of the APPs.

A copy of Our Privacy Policy is located on Our website at www.sura.com.au

Please access and read this policy. If You have any queries about how We handle Your personal information or would prefer to have a copy of Our Privacy Policy mailed to You, please ask Us.

Agent Of Insurers

In arranging this insurance, SURA Professional Risks Pty Ltd is acting under an authority given to it by insurers, and is acting as the agent of the insurer and not as Your agent.

General Insurance Code Of Practice

We proudly support the General Insurance Code of Practice.

The purpose of the Code is to raise the standards of practice and service in the general insurance industry. For further information on the Code, please visit www.codeofpractise.com.au

Not a Renewable Contract

This Clinical Trials Policy is not a renewable contract so the Policy will terminate on the expiry date indicated. If you therefore require a subsequent Policy, you will need to complete and submit a new proposal form for assessment prior to the termination of the current policy.

Section 1

Applicant Details

Name of Insured(s)

ABN

Address Details

Address

Postcode

Suburb / City

Date Established

/ /

Email

Website

Is the applicant the (please select one)

☐ Sponsor ☐ Local legal representative

If the applicant is a local legal representative, please provide details of the sponsor

Name

Address

Postcode

Suburb / City

State

Is this application for

☐ Single clinical trial (non-renewable and only for the trial period) – *Complete Section 2 Details*

☐ Multiple clinical trials (annually renewable policy) – *Complete Section 3 Details*

Section 2

Single Non-Renewable Clinical Trial

Country(ies) where clinical trial will take place

Estimated start date of trial / /

Estimated completion date of trial / /

Final patient contact / /

Protocol No

Protocol title

Study Phase (if applicable)

Product Name

ANZCTR No (if relevant)

EudraCT No (if relevant)

ClinicalTrials.gov Identifier (if relevant)

No. of Research Subjects to be enrolled by country

Country	Active	Placebo / Control

Australian Participant split (if applicable)

State	NSW	VIC	QLD	SA	WA	TAS	ACT	NT
Subjects								

Section 3

Annually Renewable Multiple Trials

Please complete for all trials that are:

- Planned (expecting to commence in proposed insurance period);
- Current (in progress);
- Completed (last patient, last contact within last 3 Years).

	Trial 1	Trial 2	Trial 3
Status			
Product name			
Protocol number			
Study title			
Phase			
Active subjects			
Placebo subjects			
Country(ies)			
Start (MM/YY)			
End (MM/YY)			

Section 3

	Trial 4	Trial 5	Trial 6
Status			
Product name			
Protocol number			
Study title			
Phase			
Active subjects			
Placebo subjects			
Country(ies)			
Start (MM/YY)			
End (MM/YY)			

If there is insufficient space to list all trials to be insured, please attach a separate list containing information as outlined above.

Section 4

Claims

Has there ever been a loss or SAE related to the product/s being trialled? ☐ Yes ☐ No

If Yes, please provide details below

Please provide the following documents with Your application (for each trial to be insured under the policy):

- Trial protocol
- Patient Informed Consent
- Copies of any contracts or agreements (excluding unaltered Medicines Australia / MTAA Clinical Trial Research Agreements

Are any trials being undertaken in:

☐ Cuba ☐ Iran ☐ North Korea ☐ Syria ☐ the Crimea Region of Ukraine

☐ any territory subject to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, the Commonwealth of Australia, United Kingdom or the United States of America?

If "Yes" to any of the above, We may require additional information to be provided to Us.

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Declaration

This Declaration must be signed by the intending insured as the Proposer(s). If the intending insured is a Company, Partnership or other business venture or involves more than one person or entity, then the person signing this declaration must be authorised to sign on behalf of all persons / entities identified as the intending insured(s).

Before completing this document, I/We have read and understood the information herein, including the Important Information.

I/We agree that this Proposal Form together with any other information supplied by me/us shall form the basis of any Contract of Insurance effected.

I/We undertake to inform the Insurer of any material alteration to this information occurring before the proposed insurance commences.

I/We declare that the statements and particulars contained in this Technology Insurance Proposal Form are true and complete and that I/We have not misstated or suppressed any material facts.

I/We understand that the Insurer is relying on information supplied herein to decide whether or not to accept or reject this risk and that no material information has been knowingly withheld.

I/We acknowledge that by submitting this completed Proposal Form (with any other information) I/We consent that the insurer may use and disclose my/our personal information in accordance with the "Privacy Statement" at the beginning of this Proposal. This consent remains valid until I/We alter or revoke it by written notice.

I/We also undertake to advise any changes to my/our personal information.

I/We authorise SURA Technology Risks or its agent to give to and obtain from other insurers, insurance reference bureaus and credit reporting agencies any information relating to the insured's credit or insurance history as well as insurance claims information obtained during the course of this contract.

Name of firm

Signed by Proposer

(This Proposal is to be signed by a Principal, Partner or Director of the Proposed Insured)

Title of signatory

Full name

Date

/ /