

Clinical Trials Proposal Form

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:

Belarus Cuba Iran North Korea Russia Syria 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.

Important Information

General Advice Warning

Any advice about this insurance that We or SURA give You is of a general nature. We do not consider Your individual objectives, financial situation or needs. It is up to You to choose the cover You need, and You should carefully read this document and any other documents that form part of the Policy before deciding whether this insurance is right for Your individual objectives, financial situation and/or needs.

Duty of Disclosure

Before the contracting insured enters into an insurance contract (referred to as "You" and "Your" in this notice), You have a duty to tell Us of anything that You know, or could reasonably be expected to know, that may affect Our decision to insure You and on what terms. You have this duty until We agree to insure You.

You have the same duty before You renew, extend, vary, or reinstate an insurance contract.

You do not need to tell Us anything that:

- reduces the risk We insure You for;
- is of common knowledge;
- We know or should know as an insurer; or
- We waive Your duty to tell us about.

If You do not tell Us something

If You fail to comply with Your Duty of Disclosure, and We would not have entered into the contract, for the same premium and on the same terms and conditions, had the failure not occurred, We may, subject to applicable law:

- be entitled to cancel Your contract or reduce the amount We will pay You if You make a claim, or both; or
- If Your failure to tell Us is fraudulent, We may refuse to pay a claim and treat the contract as if it never existed.

Subject to applicable law or unless We state otherwise, a breach of the duty by one Insured affects all insureds in these ways.

Claims Made and Notified

Section 3 – Third Party Cyber Liability are issued on a claims made and notified basis. This means that the Policy covers "Claims" that are first made against You by another person (as defined) during the Period of Insurance and notified to Us also during that Period of Insurance, after any retroactive date on the Policy. The Policy doesn't cover facts or circumstances which You first became aware of prior to the Period of Insurance, and which You knew or ought reasonably to have known had the potential to give rise to a claim against You.

Not a Renewable Contract

The 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.

Privacy

Your personal information will be collected and handled in accordance with our Privacy Policy. A copy of Our [Privacy Policy](#) is located on Our website at www.sura.com.au.

Declaration

By signing this document You represent that You are authorised to sign on behalf of all persons/entities identified as the intending insured(s). A misstatement or misrepresentation by one applicant of any material facts relevant to the Insurer's decision whether to accept or reject this risk is treated as a misstatement or misrepresentation by all applicants.

I/we have read and understood the information herein, including the Important Information and the SURA Privacy Policy.

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 declare that the statements and particulars contained in this Proposal Form are true, correct, and complete and that I/we have not omitted, misstated or suppressed any material facts.

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

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