



PROPOSAL FORM FOR CLINICAL TRIALS

THIS PROPOSAL IS FOR A
CLAIMS MADE POLICY

The policy will only respond to claims and/or circumstances, which are first made against the Insured and notified to the Insurer during the policy period. **The policy will not provide cover for:**

- Events that occurred prior to the retroactive date of the policy.
- Claims made after the expiry of the policy period even though the Wrongful Act giving rise to the claim may have occurred during the policy period.
- Claims notified or arising out of facts or circumstances notified under any previous policy or noted on the current proposal form or any previous proposal form.
- Claims made, threatened or intimated prior to the commencement of the policy period.
- Facts or circumstances in your knowledge prior to the policy period, which you knew had the potential to give rise to a claim under the policy.

 011 731 3600  info@sha.co.za  www.sha.co.za

 The Pavillion, Wanderers Office Park, 52 Corlett Drive, Illovo, 2196

DISCLOSURE

You must disclose to the Insurer all information which is material to it in deciding whether to issue insurance cover to you, including any facts or conduct which might lead to a claim being made against you. Failing to do so could affect your rights to indemnity.

If you do not understand any part of this document, please contact your Broker BEFORE YOU SIGN IT. You will be bound by the answers, which are given, and by the information provided by you in this proposal form. It is in your interest to make sure that all information is correct and properly understood.

When in doubt, disclose.

ATTACHMENTS

Before you return this form, have you included the following (please indicate by ticking the boxes):

Protocol

Research subject information and consent form

Hold harmless/indemnification agreements

Please attach details where not enough space on the declaration form

1. Details of proposed insured

Please provide the following details:

Name of proposer

Postal address

Physical address

Contact person

Tel number

Fax number

Email address

Website

Company registration number

VAT registration number

2. Detailed description and title of trial

3. Detailed description of the Proposer's involvement in the trial to be insured

4. Has approval been obtained from the Medicines Control Council and Ethics Committee?

NO YES

If NO, please provide full details

5. Will the trial be conducted in full accordance with applicable government department, medical body or pharmaceutical industry body guidelines and requirements?

NO YES

If NO, please provide full details

6. Specify the funding / budget applicable to this trial

7. Where will the trial be conducted?

8. Total number of research subjects involved in or being recruited for the trial

Category	Number of research subjects
Infants (0 – 7 years of age)	
Minors (7 – 18 years of age)	
Pregnant	
Adults (over 18 years of age which are not pregnant)	
Total	

9. Total number of batches of research subjects

10. Specify the characteristics of the participant population (e.g. gender, physical condition, etc.) and specifically indicate whether the following Research Subjects will participate in the trial:

a) Research subjects under the age of eighteen (18) years	NO	YES
b) Pregnant research subjects	NO	YES
c) Research subjects that require additional attention as outlined in Section 2.3 of the “Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa” as issued by the South African Department of Health	NO	YES
d) Other		

11. Commencement date of trail

Planned end date of trial

12. Expected length of trial

a) Per research subject:

Length of intervention / treatment period weeks

Length of "follow-up" period weeks

b) Timeframe between each batch of research subjects weeks

13. Type of testing

Mark the applicable boxes

a) Phase 1 (human pharmacology)

b) Phase 2 (therapeutic exploratory)

c) Phase 3 (therapeutic confirmatory)

d) Phase 4 (therapeutic use)

14. Describe the nature and purpose of the trial

15. Name of the drug / product being tested

16. Is the drug / product registered in North America?

NO YES

If YES, what is the FDA (Food and Drug Administration) classification?

17. Describe the intended purpose of the drug / product and how it will be used when approved

18. Briefly describe how the drug / product has been used in other applications

19. Give details of previous testing on the drug / product, including toxicity studies and explain any problems or adverse events which resulted in death, injury, illness, disease (physical or mental) to research subjects

20. Describe any losses, including reserves / payments incurred during previous testing

21. What part of the body or body system will be affected?

22. What are the possible or known side effects or complications?

23. What harm might occur if the drug / product did not work as intended?

24. How will the drug / product be administered?

25. Claims experience

1. Other than circumstances / claims / incidents which may result in any possible claims, already notified to SHA, have any claims ever been made against the proposed insured / partners / directors / members or employees for the type of cover for which you are now applying, whether in terms of this Proposal or any other proposal / policy for the same type of cover? NO YES

If YES, please provide / attach full details

2. **After enquiry**, are any of the Proposed Insured / Partners / Directors / Members or Employees aware of any circumstances which could be covered under a policy of this type, that may result in any claims, or any possible claims being made against them? NO YES

If YES, please provide / attach full details

3. Please advise of corrective measures taken to avoid recurrence of any claims or circumstances

26. Details of insurance

1. Are you at present or have you in the past been insured for Professional Indemnity? NO YES

If YES, please provide the following details and attach a copy of the Policy (please note the details of all policies if there is more than one in place)

Name of broker

Name of insurer

Date cover expires/d

Expiry of "run-off" cover (if any)

Limit of indemnity

Deductible / excess applicable

Premium

2. For the type of Insurance now being proposed, has any insurer ever:

- | | | |
|---|----|-----|
| a) declined a proposal or renewal for this practice or any partner / principal? | NO | YES |
| b) required an increased premium or imposed special terms? | NO | YES |
| c) cancelled an insurance? | NO | YES |

If YES, please provide full details

27. Quotations required

Kindly advise what limits you would like terms for:

- | | |
|--|--|
| a) Limit of indemnity (annual aggregate) | (Minimum of R 1 000 000) |
| b) Sub-limit per research subject | (Minimum of 10% of limit of indemnity) |
| c) Deductible (each and every claim) | (Minimum of R 25,000) |
| d) "No fault" or "legal liability basis: | |

(Note: Limit any one period of insurance is inclusive of costs and expenses)

DECLARATIONS

- I/we declare that after proper enquiry the statements and particulars given above are true and that I/we have not miss-stated or suppressed any material fact.
- I/we agree that this Proposal Form, together with any other material information supplied by me/us shall form the basis of any contract of insurance effected thereon.
- I/we undertake to inform Insurers of any material alteration to these facts occurring before the completion of the contract.

Signed on behalf of the Proposer

Position held at Proposer

Full name

Date

PROTECTION OF PERSONAL INFORMATION ACT

We understand that the information provided in this application for insurance and all documentation provided with it may be deemed to be personal information in terms of the Protection of Personal Information Act 2013 (the POPI Act) and we will accordingly take all reasonable steps to ensure that your information is processed / used / stored in accordance with the POPI Act and for the following purposes:

- | | | |
|--|---|---|
| <ul style="list-style-type: none"> To verify the information disclosed herein against any other source; To communicate with you directly should you request us to and in accordance with relevant regulatory requirements; To compile non-personal statistical information to assist in assessing similar risks; To assess the risk to be underwritten and, if a Policy of Insurance is issued | <p>pursuant to and based upon such information, to use the disclosed information at claims stage to assess any claims that may be made against any such Insurances;</p> <ul style="list-style-type: none"> To transmit your personal information to any affiliate, subsidiary, service provider/consultant/advisor or re-insurer so that we can provide insurance services to you and to enable us to further our legitimate | <p>interests including statistical analysis, reinsurance and credit control;</p> <ul style="list-style-type: none"> To combat insurance fraud and properly evaluate risks, we will store your personal information on a shared database created by the South African Insurance Association (SAIA) in order to verify it against available sources and databases on the system. |
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Personal information of minors (complete if applicable)

If any information provided herein relates to a Minor (i.e. a child under the age of 18) we require that a competent person (parent/legal guardian) provide consent to the processing of such information for the above purposes and for any purpose that is compatible therewith.

I,
(full name of competent person), hereby provide my consent to the processing of any information provided herein relating to

(name of minor whose personal information is disclosed herein) for the purpose as disclosed above. I further understand that I have the right to withdraw this consent at any time but that this may mean that any insurance issued pursuant to this application may be terminated and/or that any claims issued against such insurance may not be able to be finalised.

Further disclosures

Please note that there may be instances where we will be required to transfer your personal information outside South African borders, generally for purposes of furthering the Insurer's legitimate interests regarding reinsurance or for the processing of any claim that arises outside South African borders. However, before transferring your personal information, we will ensure that the entity to whom the information is being transferred is subject to similar data protection conditions as those imposed by the POPI Act failing which we will advise you accordingly and request your consent to transfer information as required.

Note that the provision of the information required/requested herein is mandatory as it is necessary for us to accurately underwrite the insurances, which you are hereby applying for, and if any information is withheld or is misrepresented the Insurer may be entitled to void any insurances issued pursuant to this application.

Although any insurance issued pursuant to this application will be reviewed annually (where appropriate) it is your responsibility to ensure that the information provided to the Insurer remains accurate and up to date, we therefore encourage you to contact us at any time to advise us of changes to the information provided.

In addition, you may contact us at any time to exercise the following rights that you have in terms of the POPI Act (subject to any regulatory obligations placed on us/Santam Ltd):

- To request that we provide you with access to your personal information held/processed by us;
- To request that we erase or correct the your personal information that we hold (where appropriate/possible);
- To request that we transfer any personal information held by us to you or to any other person/system selected by you in a structured, commonly used and machine-readable format;
- To request that we restrict the processing of your personal information for reasons provided for in the POPI Act.

Should you wish to lodge a complaint regarding our compliance with the POPI Act or in respect of the processing of your personal information, please contact the Santam Client Care department (contact details below):

Email: complaints@santam.co.za
Telephone: 0860 102 725
Fax: (021) 915 7434

Alternately, you also have the right to approach the South African Information Regulator (contact details below) should the above process not adequately address your concerns.

Email: complaints.IR@justice.gov.za
Postal address: PO Box 31533
Braamfontein, Johannesburg, 2017

Physical address:
JD House, 27 Stiemens Street
Braamfontein, Johannesburg, 2001