

Clinical Trials Liability Insurance (PROPOSAL FORM)

Important Notes:

- This proposal for insurance will be the basis of any subsequent insurance policy that we issue to you. It is essential that you answer fully and accurately all of the questions contained in this proposal, and that you provide us with any and all additional information relevant to the risk to be insured or our decision as to the acceptance of the risk or the terms upon which it should be accepted. Your failure to comply with this obligation now may result in the rejection of your claim and the avoidance of your policy when a claim is made. If you are in any doubt about the information to be given, please seek the advice and guidance of your insurance advisor or agent. Liability of the company does not commence until the proposal has been accepted and the premium has been received in accordance with the provisions of section 64VB of the insurance act, 1938.*
- All questions must be answered. If the answer to any question is none or not applicable, state NONE or NOT APPLICABLE. If space is insufficient to answer any question fully, attach a separate sheet.*
- Where applicable, please provide Products Brochures, Contract Conditions and/or Trading Conditions and Testing and/or Accreditation Certificates.*
- Proposal Form must be signed and dated by an authorised signatory of the insured.*

DETAILS: Put a (✓) mark wherever applicable

1. Name of the broker or agent (as applicable): _____

2. Information about the Insured

2.1. Proposed Insured (company name):

2.2. Business:

2.3. Length of time in business:

2.4. Complete mailing address (with PIN code):

Website:

E-mail & phone no. of the insurance contact point:

2.5. Names of all Joint Venture Partners/Collaborator:

2.6. Names & mailing address(s) of subsidiaries and stepdown subsidiaries to be covered hereunder:

3. Risk Details (regarding trial/study to be covered):

3.1. Please fill up following table, provide information for each trial/study to be covered (please attach a separate sheet in case of space constraint):

Sr. No.	Title and objective of the trial/study	Study protocol number	Sponsor of the study	Name of investigational drug & its Therapeutic segment	Clinical phase	Count of study subjects	Trial/Study duration
1							
2							
3							

3.2. Are all trials/studies in full accordance with Department of Health/Government & Pharmaceutical Industry Body Guidelines requirements with protocols approved by an Independent Ethics Committee? Yes / No

3.3. Are all trials/studies to be covered are conducted in India? Yes / No
If No then please show summaries of trials in each country

- 3.4. Are all rights of recourse retained against product manufacturers (as applicable)? Yes / No
- 3.5. Are all volunteers tested for HIV and Hepatitis prior to entering trial? Yes / No
- 3.6. Does any of the trial/study mentioned above involve infants as study subjects? Yes / No
- If yes, please provide complete details

4. Coverages Requirement:

4.1. Policy period requirement: From: _____ To: _____
(DD/MM/YY) (DD/MM/YY)

4.2. Territorial Scope of cover (tick):

☐ India ☐ Worldwide excluding USA & Canada ☐ Worldwide

4.3. Jurisdiction (tick): ☐ India ☐ Worldwide excluding USA & Canada ☐ Worldwide

4.4. Limit of Indemnity for the Policy (amount in INR):

Limit of Indemnity	Any One Event/Accident	In the Aggregate
Policy Limit		
Limit Per Subject (within overall Policy Limit mentioned above)		

4.5. Voluntary Excess/Deductible (each & every claim): INR _____

4.6. Retroactive date (applicable only for renewal policies and subject to conditions):

5. Details of Your existing insurance policy (as applicable):

5.1. Insurance company:

5.2. Policy Period: From _____ to _____

5.3. Retroactive date:

5.4. Limit of Indemnity: Aggregate: INR _____ Any One Accident: INR _____

5.5. Territorial Scope of cover (tick):

☐ India ☐ Worldwide excluding USA & Canada ☐ Worldwide

5.6. Jurisdiction (tick): ☐ India ☐ Worldwide excluding USA & Canada ☐ Worldwide

5.7. Premium paid: INR _____

5.8. No. of claims reported (if any):

5.9. Total amount of claims made: INR _____

5.10. Has any insurer ever declined to renew Liability insurance proposal? Yes / No

6. Information about adverse situation/loss/claims related to cover desired:

6.1. Please provide full details of incident(s) during the last 5 years that resulted or may result in death, injury, disease or illness to patients/subjects or volunteers.

6.2. Are you aware of any adverse event/situation/incident/loss that can lead to a claim or claim like situation under the proposed policy? ☐ Yes ☐ No If "yes", please provide complete details

7. Additional Information requested herein: Please provide the below mentioned documents with the proposal form

7.1. Copy of Study Protocol

7.2. Specimen copy of Informed Consent form

7.3. Specimen copy of SADR reporting form (serious adverse drug reaction)

8. Mandatory Information:

8.1. Additional details (compulsory):

8.1.1. Nationality: Indian / Non – Indian If Non-Indian, please specify Country:

8.1.2. Type of Organization: Corporations/ Governments /Non-Governmental Organizations Society / International Organization/ Trust /Partnership / Cooperatives /Section 25 Company

8.1.3.PAN CARD Number (10 Digit Number)

8.1.4.Sources of funds: Salary/Business /Investments Other (Please Specify)

8.1.5.GSTN No. _____

8.2. A policyholder's bank account details are mandatory to process the claim through NEFT, please provide the below details (all fields are compulsory) and provide a cancelled cheque of the proposed policyholder (should be of the bank account number mentioned below):

- Proposed policyholder's name (as per bank record): Account no.:
- Name of the bank: Branch Name:
- Address of the bank: IFSC Code of the bank:
- PAN card no. of the proposed policyholder:

STATUTORY WARNING: PROHIBITION OF REBATES

Section 41 of Insurance Act 1938 (Prohibition of rebates):

1. No person shall allow or offer to allow either directly or indirectly as an inducement to any person to take out or renew or continue an insurance in respect of any kind of risk relating to lives or property in India, any rebate of the whole or part of the commission payable or any rebate of premium shown on the policy, nor shall any person taking out or renewing or continuing a policy accept any rebate, except such rebate as may be allowed in accordance with the published prospectus or tables of the insurer."
2. Any person making default in complying with the provisions of this section shall be liable for penalty which may extend to ten lakh rupees.

Section 64 VB of the Insurance Act 1938

Commencement of risk cover under the policy is subject to receipt of premium by Tata AIG General Insurance Company Limited.

Declaration by Proposed Policyholder (in respect of all sections)

- I / We do hereby solemnly declare and state that all information given above is true to my / our knowledge. In case such information is found at any time in future to be false or misleading or it is found by the insurer that I / We have not disclosed any fact which is material to the assessment of the risk, the insurance cover granted to me / us shall be deemed to be null and void and I / We shall not be entitled to any benefit hereunder.
- I/we hereby confirm that all premiums paid / payable in future will be from bonafide sources and not paid out of proceeds of crime and that such premiums are not disproportionate to my/our income. I / we understand that the Company has the right to call for documents to establish sources of funds and to cancel the insurance policy in case I / we are found guilty by any competent court of law under any of the statutes, directly or indirectly governing the prevention of money laundering law in India.
- I / we are not Politically Exposed Persons * nor are their close relatives / family members / associates. I / we shall keep the company informed if we subsequently become a Politically Exposed Person / close relative / family member / associate of Politically Exposed Persons.
"Politically Exposed Persons" shall have the meaning assigned to it under Prevention of Money-Laundering (Maintenance of Records) Amendment Rules, 2023 as amended from time to time.
- The content of this form along with product benefits, terms/conditions and exclusions have been clearly explained to me/us. I/we have understood these and confirm to abide by the policy terms & conditions.

Date: Day Month Year

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