

Clinical Trial Insurance Policy Wording

Claims Made form

Preamble

Future Generali India Insurance Company Limited (herein called the “Company”) and the Insured (as named in the Policy Schedule) agree that

The Company will indemnify or otherwise compensate the Insured, in accordance with, and subject to the terms and conditions of this Policy, and in consideration of the this Policy, and in consideration of the payment of premium to the Company for the Period of Insurance.

The proposal made to the Company, by, or on behalf of the insured in writing shall be the basis of the Contract.

Provided that this Policy shall be valid unless it has been signed by an authorised official of the Company.

DEFINITIONS

For the Purpose of this policy, the following terms shall have the meaning as set forth hereunder:

“**Claim**” Shall mean a written demand against a Named Insured for Damages on account of an Injury which may be subject of indemnity under this policy, or written notice by a Named Insured to the Company of written demand against an Additional Insured or any Other any party for Damages on account of an injury which may be subject of indemnity under the Policy.

“**Clinical Trial**” shall mean any investigation in human subjects intended:

- To discover or verify the clinical pharmacological or other pharmacodynamics effects of one more Medicinal Products.
- To Identify and adverse reactions to one more Medicinal Products
- To Study absorption, distribution, metabolism and excretion on one or more Medicinal Products with the object of ascertaining the safety or efficiency of those products and shall include any Non-interventional Trial.

All studies conducted under a single Protocol shall be considered as one Clinical Trial regardless of the number of centres and territories involved in such studies.

“**Damages**” shall mean all form of compensatory, monetary, and statutory damages, other than punitive or exemplary damages, governmental (civil or criminal) fines or penalties, or costs of compliance with equitable relief, which an Insured shall be obligated to pay by reason of judgment or settlement for liability on account of Injury, covered by this Policy, and shall include Defence Costs.

“**Ethics Committee**” shall mean any ethics committee established and recognised as such.

“**Informed Consent**” shall mean an informed consent take part in a Clinical Trial, given by; a Research Subject, or a person with parental responsibility for a minor, or by a legal representative for a minor, or a legal representative for an incapacitated adult, only if this decision:

- Is given freely after that person is informed of the nature, significance, implications and risks of the trial; and either
- Is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or
- If the person is unable to sign or to mark a document so as to indicate his consent, said consent is given orally, in the presence of at least one witness, and recorded in writing.

References to Informed Consent include references to Informed Consent given by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.

Any Informed Consent given shall comply with the applicable guidelines including the Indian Guidelines for Good Clinical Practice formulated by Central Drugs Standard Control Organisation, India (CDSCO)

“Licensing Authority” shall mean any licensing authority pursuant to Indian law, regulations and practices set up by the responsible government authority, including, but not limited to the Drugs Controller General of India (DCGI) and Central Drugs Standard Control Organisation, India (CDSCO)

“Limit of Liability” shall mean the amount set forth in the Policy Schedule which shall be the Company's maximum liability in respect of each and every Claim and in the aggregate for all Claims under this Policy incurred during one Period of Insurance, irrespective of the number of Insured's and / or the number of Claims. Defence Costs are included.

“Non-interventional Trial” shall mean a study of one or more Medicinal Products which have a marketing authorization, where the following conditions are met cumulatively:

- The products are prescribed in the usual manner in accordance with the terms of that authorization,
- The assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a protocol but falls within current practice,
- The decision to prescribe a particular medicinal product is clearly separated from the decision to include the patient in the study,
- No diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question,
- Epidemiological methods are to be used for the analysis of the data arising from the study.

“Medicinal Product” shall mean any substance or combination of substances presented for treating or preventing disease in human beings or any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

“Protocol” shall mean a written document that describes the objectives, design, methodology, statistical considerations and organisation of a Clinical Trial.

“Injury” shall mean bodily injury, sickness or disease sustained by a person, including death.

“Employee” shall mean any person under a contract of service or apprenticeship with the Named Insured, or any of the following persons while working for the Named Insured: labour only

subcontractor or person supplied by him, any self-employed person, any person who is borrowed by or hired to the Insured including persons on secondment from overseas countries, any trainee or person undergoing work experience, prospective employees being assessed by the Named Insured as to their suitability for employment, any voluntary helper.

“Retention/Deductible” shall mean the amount set forth in the Policy Schedule, which is the first part of all Damages, payable in respect of each and every Claim, to be borne by the Insured before the Company shall be liable to make any payment.

“Insured” shall mean the Named Insured as stated in the Policy Schedule, any Additional Insured’s or any Other Party as far as covered by this Policy.

“Additional Insured’s” shall mean the Additional Insured’s as stated in the Policy Schedule or stated in the Endorsement attached to Policy document.

“Defence Costs” shall mean reasonable legal fee, costs and other expenses incurred by or on behalf of an Insured in connection with the defence of any Claim, excluding the salaries, wages and benefits of the Insured’s Employees (including, without limitation, the Insured’s in-house attorneys) and the Insured’s administrative expenses, only with respect to coverage provided by this Policy.

“Other Parties” shall mean upon request of the Named Insured any partner, director or Employee of the Named Insured, the personal representatives of any party specified above, the personal representatives of the Insured.

“Medicinal Purpose” shall mean

- Treatment or preventing disease
- Diagnosing disease or ascertaining the existence degree of or extent of a physiological condition
- Assisting with or altering in any way the process of contraception or investigating or participating in methods of contraception
- Inducing anaesthesia
- Otherwise preventing or interfering with the normal operation of a physiological function

“Research Subject” shall mean an individual legally resident within the geographical limits of India, whether a patient or not, who participates in a Clinical Trial either as a recipient of an investigational Medicinal Product or of some other treatment or product, or without receiving any treatment or product, as a control.

“Compensation Agreement” Shall mean any agreement entered into between the Named Insured and any Research Subject

- In accordance with requirements of the Ethics Committee and/or the responsible Licensing Authorities including but not limited to the Drug Controller General India (DCGI) and Central Drugs Standard Control Organisation (CDSCO)
- Any other agreement of the like nature which provides for compensation for injury and is notified to and agreed by the company

“Extended Reporting Period” Shall mean the period of time after the end of the Period of Insurance for reporting Claims which have taken place prior to the end of the Period of Insurance but which the Insured became aware of after the Period of Insurance.

SCOPE OF COVER

1. Legal Liability

Within the Limit of Liability, the Company will indemnify the Named Insured against legal liability whether imposed by operation of law or under the terms of any Compensation Agreement to pay Damages in respect of Injury to any Research Subject caused by or arising out of participation by the Research Subject in any Clinical Trial

- Which is commencing within the Period of Insurance, and
- Which is conducted in the geographical limits of India, and
- Which has been notified to and accepted by the Company in writing, and for which any Claim is first made against an Insured and notified to the Company during the Period of Insurance or within 90 days following the expiration date of the Period of Insurance.

2. Limit of Liability

The Company's liability in respect of all Claims under this Policy shall not exceed the Limit of Liability, inclusive of Defence Costs.

EXTENSIONS TO THIS POLICY - INDEMNITIES TO OTHER PARTIES

A. Additional Insured's

Coverage as set out in above shall also be provided to an Additional Insured, as stated in the policy schedule with the specific agreement of the insurer provided that

- The Additional Insured conducts a Clinical Trial on behalf of the Named Insured, and it is held liable for any Injury in such capacity, and
- The Named Insured would have been entitled to indemnity under this Policy if the claim had been made against the Named Insured.

B. Other Parties

Coverage as set out in above shall also be provided to an Other Party, provided that

1. As regards a partner, director or Employee of the Named Insured:

- Liability has incurred in such capacity, and

The Named Insured would have been entitled to indemnity under this Policy in respect of such liability if the Claim had been made against the Named Insured as though each partner, director or Employees as individually named as the Insured in this Policy, and

- No indemnity will be provided to any medical or dental practitioner while working in a professional capacity as such a practitioner.

2. As regards the personal representatives of any part specified above:

- The respective party would have been indemnified under this Policy;
3. As regards personal representatives of the Insured:
- Liability has incurred by the Insured and provided that
4. Each such party shall observe fulfil and be subject to the terms and conditions of this Policy insofar as they can apply, and
5. Such personnel shall not be entitled to indemnity under any other policy.

c. **Extended Reporting Period**

The Company agrees to provide the Insured with an additional notification period of Claims which are first made against the Insured during the Period of Insurance provided that such Claims is notified to the Company within the Extending Reporting Period of 30 days

GENERAL EXCLUSIONS APPLICABLE TO THE POLICY:

The Company shall not be liable for:

1) **Persons Employed**

Any liability for Injury to any Employee unless such Employee is a Research Subject in any Clinical Trial

2) **Contractual Liability**

Any liability assumed by the Insured solely under the terms of an agreement except liability that attaches under a Compensation Agreement.

3) **Penalties, Liquidated and Punitive damages**

Any liability in respect of

- Fines, penalties, compliance cost or liquidated damages
- Punitive, exemplary or aggravated damages and/or any additional damages resulting from the multiplication of compensatory damages

4) **Retention Clause**

The amount of the Retention specified in the Policy Schedule

5) **Ethics Committee and Licensing Authority approval**

Any liability arising from a Clinical Trial that has not received approval from an Ethics Committee and all required authorisations, approvals from all responsible Licensing Authorities, including, but not limited to the Drug Controller General India (DCGI) and Central Drugs Standard Control Organisation (CDSCO)

6) **Failure of intended Medicinal Purpose**

Any liability arising from the failure of any Medicinal Product to have its intended Medicinal Purpose

7) **Intended or Expected Injury**

Any liability arising from any Injury that was intended or expected by the Insured

8) **Departure from Protocol**

Any liability arising from any departure from the agreed Protocol or requirements of the Ethics Committee and/or the responsible Licensing Authorities including but not limited to the Drug Controller General India (DCGI) and Central Drugs Standard Control Organisation (CDSCO)

9) **Failure to obtain Informed Consent**

Any liability arising from any failure to obtain Informed Consent from any Research Subject

10) **Continued use of Medicinal Product**

Any liability arising out of the continued use of a Medicinal Product after the completion of the Clinical Trial

11) **Pre-existing medical conditions**

Any liability arising from the aggravation of existing health impairments, or deterioration of any physical or mental condition, which would, on the balance of probabilities, have occurred or continued whether or not the Research Subject had participated in the Clinical Trial

12) **Diseases**

Any claim arising from Hepatics or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or any way related to Acquired Immuno Deficiency Syndrome or any syndrome or condition of a similar kind however it may be named.

Any claim arising from any condition directly or indirectly caused by or associated with Creutzfeldt - Jakob disease (CJD) variant Creutzfeldt - Jakob disease (vCJD) or new variant Creutzfeldt - Jakob disease (nvCJD).

13) **Radioactive Contamination**

Any liability in respect of any Injury or any legal liability of whatsoever nature directly or indirectly caused by or contributed to or arising from

- Ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel:
- The radioactive, toxic, explosive or other hazardous properties on any explosive nuclear assembly or nuclear component thereof.

14) **War**

Any liability in respect of any consequence of war invasion act of foreign enemy hostilities (whether war be declared or not) civil war, rebellion, revolution, insurrection, military or usurped power, nationalisation, confiscation, requisition, seizure or destruction by the government or any public authority

15) Terrorism Damage Exclusion Warranty

Notwithstanding any provision to the contrary within this Insurance it is agreed that this insurance excludes loss, damage cost of expense of whatsoever nature directly or indirectly caused by, resulting from or in connection with any act of terrorism regardless of any other cause or even contributing concurrently or in any other sequence to the loss.

For the purpose of this endorsement an act, or terrorism means an act, including but not limited to use of force or violence and/or threat thereof, of any person or group(s) of persons whether acting alone on or behalf or in connection with any organization(s) or government(s), committed for political, religious, ideological or similar purpose including the intention to influence any government and/or put the public, or any section of public in fear.

The warranty also excludes loss, damage, cost of expenses or whatsoever nature directly or indirectly caused by, resulting from or in connection with any action taken in controlling, preventing, suppressing or in way relating to action taken in respect of any act of terrorism.

GENERAL CONDITIONS

Conditions Precedent to liability

The observance and fulfilment of the terms and conditions of this Policy shall be conditions precedent to any liability of the Company to make any payment under this Policy

Claims procedure

In the event of any Claim or circumstance which may give rise to a Claim under this Policy the Named Insured or any other poly claiming indemnity under this Policy shall:

- Give written notice to the Company with full particulars as soon as reasonably practicable;
- Make no admission of liability or offer promise of payment without the Company's written consent;
- Inform the Company immediately of any impending prosecution inquest or fatal inquiry or civil proceedings and send to the Company every relevant document unanswered;
- Produce to the Company such books of account or other business books or documents or such other proofs as may reasonably be required by the Company for investigating or verifying the Claim.

Each of the Additional Insured's and the Named Insured accepts that the Named Insured shall have the sole right to make a Claim hereunder (whether on its own behalf or on behalf of an Additional Insured) and it shall be a condition precedent to any liability of the Company under this Policy that the Named Insured and not an Additional Insured shall have made any such Claim.

STANDARD TERMS AND CONDITIONS

Incontestability and Duty of Disclosure

The Policy shall be null and void and no benefits shall be payable in the event of untrue or incorrect statements, misrepresentation, misdiscription or on non-disclosure in any material particular in the proposal form, personal form, personal statement, declaration and

connected document, or any material information having been withheld, or a claim being fraudulent or any fraudulent means or devices being used by the insured or any one acting on his behalf to obtain any benefit under this policy

Alterations in risk

If at any time anything shall occur, or be done materially affecting the risk insured, the Insured shall give notice in writing to the Company as soon as is reasonably practicable.

Arbitration

If any dispute or difference shall arise as to the quantum to be paid under this policy (liability being otherwise admitted) such difference shall independently of all other questions be referred to the decision of the sole arbitrator to be appointed in writing by the parties to or if they cannot agree upon a single arbitrator within 30 days of any party invoking arbitration, the same shall be referred to a panel of three arbitrators, comprising of two arbitrators, one to be appointed by each of the parties to the dispute/difference and the third arbitrator to be appointed by such arbitrators and arbitration shall be conducted under and in accordance with the provisions of the Arbitration and Conciliation Act 1996 as amended from time to time and for time being in force.

It is clearly agreed and understood that no difference or dispute shall be referable to arbitration as hereinbefore provided, if the Company has disputed or not accepted liability under or in respect of this Policy.

It is hereby expressly stipulated and declared that it shall be a condition precedent to any right of action or suit upon this policy that the award of such arbitrator/arbitrators of the amount of the loss or damage shall first be obtained.

Bankruptcy

Bankruptcy or insolvency of the Insured or of the Insured's estate will not relieve the Company of its obligations under this Policy.

Currency Clause

All Limits of Liability, premiums and other amounts as expressed in this Policy are in Indian Rupees.

Cancellation

The Company may at any time cancel the Policy on grounds of mis-representation, non-disclosure of material facts, fraud or non-cooperation by the insured by sending thirty/forty five days' notice in writing to the insured at his last known address in which case the Company shall return to the insured a proportion/ pro-rata portion of the premium corresponding to the unexpired period of insurance provided that if no claim has been paid under the policy.

The policy may also be cancelled by the insured at any time by giving thirty/forty five day's notice in writing to the Company and in such event the Company shall allow refund of premium

at Company's short period premium calculation as given below provided no claim has occurred up to the date of cancellation.

Table of Short Period Rates	
Period of Risk (days up to)	Amount of premium to be retained by the Company
7	10%
30	25%
60	35%
90	50%
120	60%
180	75%
240	85%
Exceeding 240	100%

Other Insurances

If, at the time of any Claim, there is, or but for the existence of this Policy, would be any other policy of indemnity or insurance in favour of or effected by or on behalf of the Insured applicable to such claim, then the Company shall not be liable to pay or contribute more than its rateable proportion of any loss or damage.

Limitation Period

If the Company shall disclaim liability to the Insured for any claim hereunder and such claim shall not within 12 Calendar months from the date of such disclaimer have been made a subject matter of a suit in a court of law then the claim shall for all purposes be deemed to have been abandoned and shall not thereafter be recoverable hereunder

Policy Interpretation

Unless otherwise agreed the interpretation and meaning of the provisions of this Policy shall be determined in accordance with the law of India.

The headings and titles of paragraphs in this Policy are included for descriptive purposes only and do not form part of this Policy for the purpose of its interpretation.



In this Policy, references to any statute or regulation shall be to that statute or regulation as amended or re-enacted from time to time.

Reasonable Precautions

The Insured shall take all reasonable precautions to prevent accidents and prevent or cease any activity which may give rise to legal liability and shall take all reasonable steps to observe and comply with all statutory or local authority laws, obligations and requirements.

Rights of the Company

The Company shall be entitled at their discretion to take over and conduct in the name of the Insured the defence or settlement of any Claim and to take proceedings at their own expense and for their own benefit, but in the name of the Insured, to recover compensation or secure indemnity from any third party in respect of any Injury to which this Policy applies.

The Insured shall give all consent, information and assistance required Provided that all disputes which may arise between the Company and the Insured about the defence or settlement of any Claim or operation of any Compensation Agreement shall be referred to Arbitration

The Company may at any time pay the Limit of Liability (less any sums already paid as compensation) or any lesser amount for which at the absolute discretion of the Company any Claim or all Claims caused by or arising out of or in connection with a Clinical Trial can be settled. The Company will then relinquish control of such Claim or Claims and be under no further liability in respect thereof except for costs and expenses for which the Company may be responsible prior to the date of such payment.

Sanction and Embargo Clause

This policy does not provide any insurance coverage nor provide any benefit hereunder to the extent that the provision of such insurance coverage and/or the provision of such benefit would expose the insurer to any applicable sanction laws.