

Clinical Trial (Professional Liability) Insurance

(Sample wording; to be finalized with the consultation of reinsurer)

1. Preamble and Operative clause

Whereas the Insured named in the Schedule hereto by a proposal and declaration has applied to the SBI General Insurance Company Limited for the insurance hereinafter contained and has paid the premium as consideration for this insurance.

The Company hereby agrees, subject to the terms, conditions and exclusions herein contained or endorsed or otherwise expressed hereon, to indemnify the Insured to the extent and in the manner specified herein.

2. Definitions**2.1 Personal damages**

Personal damages are all damages as a result of death, injury or other harm to the health of the trial subjects.

These also include the economic consequences of insured personal damages, namely costs, loss of earnings taking into account the economic livelihood, damages sustained by the household, loss of maintenance payments (breadwinner damages), together with nominal damages (reparations).

2.2 Material damages

Material damages are all damages as a result of destruction, damage to or loss of material goods together with any resulting damage to the property of the injured party.

2.3 Damages arising from breaches of data protection

Breaches of data protection are material and nominal damages that arise from violations to personal integrity.

2.4 Drug products

Drug products are the medicinal products as described in the Drugs And Cosmetics Act, 1940 and which are to be tested in the clinical trial.

2.5 Trial series

A trial series is a group of several clinical trials on one active ingredient or one illness.

2.6 Clinical trial

“Clinical trial” means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug. (Section 122DAA of Drugs and Cosmetics Rules, 1945)

2.7 Trial subject

Those persons (patients or healthy volunteers) who voluntarily take part in a clinical trial, whether they belong to the groups to which the Drug product is administered for testing or to a control group

2.8 Sponsor (policyholder)

Any person or organization assuming responsibility for initiating, managing or financing a clinical trial.

3. Scope of the insurance policy

3.1 Object of the insurance policy

The insurance company offers insurance coverage in the event that, during an insured clinical trial carried out by the policyholder or on its behalf, any trial subjects involved are killed, physically injured, or suffer harm to their health (personal damages) or that any trial subjects suffer material damage in relation to the clinical trial.

3.2 Scope of the insurance policy

3.2.1 *Personal damages*

Insurance coverage is intended for personal damages suffered by a trial subject in relation to a clinical trial. The insurance coverage also extends to claims for personal damages caused by procedures carried out on trial subject in relation to the clinical trial on the Drug product.

The insurance company shall provide compensation for the damage actually occurred. The trial subject or, in the event of death, the persons supported by him/her, shall receive such compensation that he/she would receive on the basis of the legal requirements if a party were found liable towards him/her.

Should any illnesses that have arisen independently of the clinical trial or any other causes have played a role in the personal damages, the compensation shall only be paid in proportion to the part of the clinical trial relevant to the personal damages.

3.2.2 *Material damages*

The company shall also provide compensation for material damages suffered by the trial subject in relation to the clinical trial.

3.2.3 *Damages arising from breaches of data protection*

Insurance coverage exists for damages suffered from breaches of data protection in relation to the insured clinical trial. Such damages shall be considered as personal damages.

3.2.4 *Cost of expert evaluations and reports*

In insured cases, the insurance company shall bear the costs of any evaluation or report by an expert it has commissioned.

3.2.5 *Other insurance benefits*

Benefits provided by the insurance company, inclusive of related damage and default interest, mitigation, expert, legal, court, arbitration, and commission costs, compensation for the parties and all other insured costs, are limited to the insured amount Or sublimit stated in the policy, less the agreed excess.

3.3 Territorial coverage and prescription

The insurance includes, within the insured study, those clinical investigations that are carried out in India within the duration of the contract.

The coverage includes damages that occur during the insured period (i.e. in the duration of the contract and the post-trial insurance coverage).

In cases of doubt the personal damages are considered to have occurred at the time when the trial subject first consulted a physician for symptoms that on this occasion or subsequently were proved to be symptoms of the personal damages concerned.

Following expiry of the contract personal damages will also be covered under the conditions of the contract if they occur within 60 months following the expiry of the contract (post-trial insurance coverage).

4. Restrictions to the scope of the insurance policy

The insurance coverage does not extend to claims of the following nature:

- a) Personal damages and a deterioration of the existing state of health which would have occurred or persisted even without participation in the clinical trial;
- b) Personal damages that occurred because the trial subject deliberately, or apparently deliberately, contravened the express instructions of the people in charge of carrying out the clinical trial;
- c) Compensation for 'punitive damages';
- d) Damages arising from substances/formulations or preparations listed by the insurer (the insurance company).

These substances/formulations or preparations must be listed by name in the "Insurance certificate for the attention of the ethics committees".

Should contraceptive drugs be used as the trial drug or as a compulsory co-medication in the context of a clinical trial, any damages attributable to these contraceptives shall be covered.

- e) Personal damages to a patient in the control group, insofar as they are attributable to the application of a Drug product that has already been licensed for this indication. However, this does not exclude claims for personal damages attributable to a breach of the obligation to exercise due care by the policyholder or a third party commissioned by it to carry out the clinical trial.
- f) Personal damages to a patient that do not exceed a certain degree of adverse reactions that are to be expected from the trial drug according to the current state of medical knowledge, insofar and to the extent that comparably serious damages could have occurred if the patient had undergone a standard therapy to treat his illness.
- g) Personal damages to a patient that do not exceed a certain degree of adverse reactions that are to be expected from the trial drug according to the current state of medical knowledge, in the case of illnesses that ordinarily have a fatal outcome and insofar as no standard therapy exists to treat that illness.

5. Premium

5.1 Basis for calculating the premium

The premium is calculated on the basis of the number of trial subjects taking part in the insured study or clinical trial for the duration of the contract.

5.2 Payment of premium and due balance

The provisional premium mentioned in the policy falls due on the first of policy period.

The definitive premium is calculated at the end of the contract or after the contract has been cancelled. For this the policyholder must supply the necessary information; the insurance company may consult all relevant documents to check this information. Supplementary premiums and reimbursements fall due for payment on delivery of the balance statement to the policyholder.

6. Obligations

6.1 Obligations of the policyholder

a) Should the policyholder carry out the clinical trial itself, it is obliged:

(i) To comply with the Indian legislation related to drugs

(ii) To inform the trial subjects about the existence of the obligations incumbent upon them as listed in paragraph 6.2 below.

b) Should the policyholder commission a third party to carry out the clinical trial, it must ensure that the third party adheres to the obligations mentioned in paragraph 6.1 letter a of these requirements.

c) Should any event occur whose probable consequences may affect this insurance, the policyholder must report it to the insurance company without delay. The insurance company must be notified of a death occurrence early enough so that it can, if necessary, arrange for a post-mortem at its own expense before the burial (subject to the rights of the deceased's family).

d) The policyholder is obliged, to the extent that it is able, to help the insurance company to ascertain the facts and reduce the damages.

e) On the request of the insurance company, the investigator must be instructed to draft a report on the personal damages and, after completion of the medical treatment, a final report, with the consent of the trial subject; in addition, it must be ensured that all other reports by the investigator requested by the insurance company are provided. In insured cases the insurance company bears the costs of the report, otherwise these are borne by the policyholder.

f) On condition that the personal damage has been reported and the trial subject has given consent, the investigator or any other physicians who are treating or examining the trial subject for other reasons, and the social insurance providers or any other insurer, if providing insurance that also covers personal damages, are to be authorized to provide the insurance company with information on request.

g) The policyholder is obliged to ensure that well-ordered records are kept about the trial subject. The records must in particular be kept in such a way that, should any damage to health occur, the events of the trial can be reconstructed for individual cases.

6.2 Obligations of the trial subject

- a) For the duration of the clinical trial, the trial subject must inform the investigator at the next visit about any other illnesses or complaints that have arisen in the meantime and about any medication taken for such illnesses or complaints.
- b) Personal damages that may have occurred as a consequence of the clinical trial must be reported to the investigator without delay.
- c) The trial subject must take or submit to all the appropriate measures that help to identify the cause and the extent of the damage that has occurred, and that help to reduce such damage.

6.3 Breach of obligations

Should the policyholder, the third party commissioned by the policyholder to carry out the clinical trial, or the trial subject, breach the obligations incumbent upon them under the terms of this contract (cf. paragraphs 6.1 and 6.2) the insurance coverage shall cease, subject to the contents of paragraph 2 below, unless they can prove that the violation under the circumstances should be considered as accidental or that the damage would have occurred even had the obligations been fulfilled.

The breach of the obligations imposed by the insurance company on the policyholder or on the third party commissioned by it to carry out the clinical trial (paragraph 6.1), only entails the right of recourse by the insurance company against the policyholder, however not the cancellation of the insurance coverage of the trial subject. In such cases, under the insurance contract, the trial subject has a right to claim directly from the insurance company. The insurance company cannot make objections that arise from the insurance contract or from the Indian Law on insurance contracts against the trial subject. The policyholder must reimburse the insurance company for the compensation paid.

7. Miscellaneous

7.1 Contract duration

The present contract is concluded for the duration mentioned in the contract details and ends on completion of the clinical trial.

Should the clinical trial not be completed by the planned expiry of the contract, the policyholder must notify the insurance company without delay so that it can extend the contract accordingly.

7.2 Reports to the company

All reports to the insurance company must be made in writing and sent to the appropriate office or the Indian head office of the insurance company.

7.3 Claim entitlement

The policyholder is entitled to exercise the rights under the insurance contract. However, the insurance company has the right to pay the trial subject the compensation directly and without deducting any excess; in such a case the policyholder must refund the excess to the insurance company, waiving any objections (subject to paragraph 6.3).

All rights and obligations applicable to the policyholder and the trial subject are applicable to their legal successors.

The insurance claims may not be transferred or pledged without the express consent of the insurance

company.

- 7.4 Any dispute concerning the interpretation of the terms, conditions, limitations and/or exclusions contained herein is understood and agreed to by both the Insured and the Insurance Company to be subject to Indian Law. Each party agrees to submit to the exclusive jurisdiction of the Courts of India and to comply with all requirements necessary to give such Court the jurisdiction. All matters arising hereunder shall be determined in accordance with the law and practice of such Court.
- 7.5 The Insurance Company may at any time cancel the Policy by sending the Insured 15 days notice by registered letter, at the Insured's last known address and in such event the Insurance Company shall refund to the Insured a pro-rata' premium for unexpired period of Insurance.

The Insured may also at any time cancel the Policy by giving a written notice to the Insurance Company and in such event the Insurance Company shall allow refund of premium at the Insurance Company's short period rates as per the Table given here below, provided no claim has occurred up to the date of cancellation.

Policy run period	% of Annual Premium Refundable
Up to one month	75% of annual rate
Up to three months	50% of annual rate
Up to six months	25% of annual rate
Exceeding six months	Nil

The Insurance Company shall not be bound to accept any renewal premium nor to give notice that such is due.

- 7.6 In no case whatsoever shall the Insurance Company be liable for any loss or damage after the expiry of 12 months from the happening of the loss or damage unless the claim is the subject of pending action or arbitration; it being expressly agreed and declared that if the Insurance Company shall disclaim liability for any claim hereunder and such claim shall not within 12 calendar months from the date of the disclaimer have been made the 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.
- 7.7 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 a sole arbitrator to be appointed in writing by the parties thereto 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 two arbitrators and the arbitration shall be conducted under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996.

It is clearly agreed and understood that no dispute or difference 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 by such arbitrator/ arbitrators of the amount of the loss or damage shall be first obtained.

Grievances:

The Grievance Redressal Cell of the SBI General looks into complaints from Insured. The Insured may approach the person nominated as 'Grievance Redressal Officer' with the details of his grievance. Name, address, e-mail ID and contact number of the Grievance Redressal Officer appears on our website.

Further, the Insured may approach the nearest Insurance Ombudsman for redressal of the grievance.

List of Ombudsman offices with contact details are attached for ready reference. For updated status, please refer to website www.irdaindia.org.

Offices	Areas of Jurisdiction	Addresses of the Ombudsman Offices
Ahmedabad	Gujarat and Union Territories of Dadra & Nagar Haveli and Daman and Diu.	2nd Floor, Shree Jayshree Ambica Chambers,
		Nr. C U Shah College, 5, Navyug Colony, Ashram Road,
		AHMEDABAD380014 Tel: 27546150, Fax: 079-27546142
		Email: insombalhd@rdiffmail.com
Bhopal	Madhya Pradesh and Chattisgarh.	1st Floor, 117, Zone II (Above D M Motors Pvt. Ltd.), Maharana Pratap Nagar, BHOPAL462 011 Tel: 2578100, 2578102, 2578103, Fax: 0755-2578103 Email:insombmp@satyam.net.in
Bhubaneswar	Orissa.	62, Forst Park, BHUBANESWAR751 009. Tel: 2535220 Fax: 0674-2531607 Email:susantamishra@yahoo.com, ioobbsr@vsnl.net
Chandigarh	Punjab, Haryana, Himachal Pradesh, Jammu & Kashmir and Union territory of Chandigarh.	S.C.O No.101,102 & 103, 2nd Floor,
		Batra Building, Sector 17 D, CHANDIGARH160 017
		Tel: 2706196 EPBX:0172-2706468 Fax: 0172-2708274
Chennai	Tamil Nadu and Union Territories - Pondicherry Town and Karaikal (which are part of Union Territory of Pondicherry).	Fatima Akhtar Court , 4th Floor, 453 (Old 312) Anna Salai, Teynampet, CHENNAI600 018 Tel: 24333678, 24333668, 24335284 Fax: 044-24333664 Email:insombud@md4.vsnl.net.in
Delhi	States of Delhi and Rajasthan.	2/2 A, Universal Insurance Bldg, Asaf Ali Road,
		NEW DELHI110 002 Tel: 23239611, Fax: 011-23230858
		Email: insombudsmandel@netcracker.com
Hyderabad	Andhra Pradesh, Karnataka and Union Territory of Yanam - a part of the Union Territory of Pondicherry.	6-2-46, Yeturu Towers, Lane Opp. Saleem Function Palace,
		A C Guards, Lakdi-Ka-Pool, HYDERABAD500 004
		Tel: 55574325, Fax:040-23376599 Email:insombud@hd2.vsnl.net.in
Kochi	Kerela and Union Territory of (a) Lakshadweep (b) Mahe-a part of Union Territory of Pondicherry.	2nd Floor, CC 27/2603 Pulinat Bldg,
		Opp. Cochin Shipyard, M G Road,
		ERNAKULAM682 015 Tel: 2373334, 2350959, Fax:0484-2373336
		Email:insuranceombudsmankochi@hclinfnet.com
Kolkata	West Bengal, Bihar, Sikkim, Jharkhand and Union Territories of Andaman and Nicobar Islands.	North British Building 29, N S Road, 3rd Floor, KOLKATTA700 001
		Tel: 22212666, 22212669, Fax:033-22212668
Lucknow	Uttar Pradesh and Uttaranchal.	Jeevan Bhavan, Phase 2, 6th floor, Nawal Kishore Road,
		Hazaratgani, LUCKNOW226001 Tel: 0522-2201188, 2231330, 2231331 Fax:0522-2231310 E-mail: iooblko@sancharnet.in
Mumbai	Maharashtra and Goa.	3rd Floor, Jeevan Seva Annexe (above MTNL),
		S V Road, Santacruz (W), Mumbai-400 054
		Tel: 26106889, EPBX:022-26106889 Fax:022-26106052, 26106980 Email:ombudsman.i@hclinfnet.com
Guwahati	Assam, Meghalaya, Manipur, Mizoram, Arunachal Pradesh, Nagaland and Tripura.	Aquarius Bhaskar Nagar, R G Baruah Road,
		GUWAHATI 781 021 Tel: 2413525 EPBX:03612415430
		Fax: 0361-2414051

INSURANCE IS THE SUBJECT MATTER OF THE SOLICITATION