

Clinical Trial (No Fault) 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.

2. Cover

The SBIGIC hereby agrees, subject to the terms, conditions and exclusions herein contained or endorsed or otherwise expressed hereon, to indemnify the Insured against all sums in excess of the Deductible that the Insured shall become liable to pay as damages or compensation and claimants costs and expenses in respect of any Claim made by Research Subjects for Bodily Injury caused by an Occurrence happening after the Retroactive Date within the Policy Territory and arising out of the Business. Provided that:

- 2.1 such Claim is first made in writing against the Insured during the Period of Insurance and is notified to the SBIGIC during the Period of Insurance; and
- 2.2 all Bodily Injury resulting or alleged to have resulted from the same Trial shall be considered as resulting from one Occurrence and as having occurred during the Period of Insurance in which the first Claim is made against the Insured irrespective of the number of claimants or the period over which such Bodily Injury is likely to result in a Claim or Claims being made against the Insured at some future date; and
- 2.3 the Insured has offered and the Research Subject has agreed to abide by the Conditions of Compensation.

The SBIGIC will also pay Legal Costs in addition to the Limits of Indemnity.

3. Definitions

3.1 The Insured shall mean any person or company named in the Schedule and shall include:

- 3.1.1 at the request of the Insured, any director or partner whilst acting in their respective capacities for the Insured;
- 3.1.2 at the request of the Insured, any employee of the Insured including Medical Persons but only whilst acting within the scope of their duties;
- 3.1.3 at the request of the Insured, any past employee who acted for the Insured and who agrees to be bound by the terms of this Policy;
- 3.1.4 subject to the prior written agreement of the SBIGIC, any sub-contractor, doctor, consultant, physician, hospital or contract research organisation or nurse who will be performing work for the Insured in respect of a Trial covered by this Policy;
- 3.1.5 subject to the prior written agreement of the SBIGIC, any Ethics Committee or its members that has approved a Trial which is the subject of this Policy,

but only in respect of Claims arising out of a Trial covered by this Policy.

3.2 Business shall mean the Business stated in the Schedule.

- 3.3 Bodily Injury shall mean personal injury, sickness, disease or death and shall include, but not by way of limitation, mental injury, mental anguish and shock.
- 3.4 Occurrence shall mean an accident or event including continuous or repeated injurious exposure to substantially the same general conditions which results during the Period of Insurance in Bodily Injury neither expected nor intended from the standpoint of the Insured.
- 3.5 Legal Costs shall mean all the costs and expenses (including any fees or disbursements of any Independent Lawyer) incurred by or on behalf of the Insured with the written consent of the SBIGIC in relation to any Occurrences which may be the subject of indemnity under this Policy.
- 3.6 Medical Persons shall mean Licensed Physicians, Doctors, Medical Nurses and Dentists.
- 3.7 Deductible shall mean the amount(s) stated in the Schedule which the Insured shall pay in respect of all damages, compensation, claimant's costs and expenses and Legal Costs before the SBIGIC shall be liable to make any payment.
- 3.8 Claim shall mean:
- 3.8.1 the receipt by the Insured of any written demand for compensation made against the Insured by or on behalf of a Research Subject;
- 3.8.2 any writ, statement of claim, summons, application or other originating legal or arbitral process, cross-claim, counter claim or third or similar party notice served upon the Insured containing a demand for compensation made by or on behalf of a Research Subject.
- 3.9 Research Subject shall mean any person participating in a Trial and shall include their dependants, heirs, executors, administrators and legal representatives.
- 3.10 Trial shall mean any Clinical Trial or Healthy Volunteer Study which complies with the statutory requirements or guidelines of the relevant person, authority, department or public or private body in the country in which the Trial occurred.
- 3.11 Independent Lawyer shall mean a judge, retired judge, Advocate.
- 3.12 SBIGIC shall mean SBI General Insurance Co Ltd.
- 3.13 Serious Adverse Event shall mean any untoward medical occurrence that at any dose:
- 3.13.1 Results in death;
- 3.13.2 Is life-threatening;
- 3.13.3 Requires in-patient hospitalisation of prolongation of existing hospitalisation;
- 3.13.4 Results in persistent or significant disability/incapacity; and or
- 3.13.5 Is a congenital anomaly or birth defect
- 3.14 Life-threatening shall mean an event in which the patient was at risk of death at the time of the event; it does not mean an event which hypothetically might have caused death if it were more severe.
- 3.15 Schedule shall mean the Certificate of Insurance and Schedule issued and signed by SBIGIC.
- 3.16 Policy shall mean this policy wording, the Schedule, any endorsements attaching to this policy wording and the Proposal.
- 3.17 Premium shall mean the total amount stated as Premium in the Schedule and in any endorsement to this Policy.

4. Extensions

Unless otherwise stated the following Extensions are subject always to the terms, Conditions and Exceptions contained in this Policy:

4.1 Manslaughter Defence Costs (Ethics Committee)

The SBIGIC will indemnify the Ethics Committee or any member thereof in respect of legal costs and expenses incurred with the SBIGIC written consent in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) as a result of alleged manslaughter arising from any event which may be the subject of indemnity under this Policy.

PROVIDED THAT

4.1.1 the proceedings relate to an offence alleged to have been committed during the Period of Insurance and in the course of the Business;

4.1.2 the SBIGIC will not provide indemnity:

(a) for fines or penalties of any kind;

(b) in respect of proceedings consequent upon:

(i) any deliberate act or omission;

(ii) Bodily Injury sustained by any employee of the Insured arising out of and in the course of employment by the Insured in the Business;

(iii) the ownership, possession or use by or on behalf of the Insured or any person entitled to indemnity of any mechanically propelled vehicle while being used in circumstances where insurance or security is required by law.

5. Exceptions

The SBIGIC shall not be liable for

5.1 any loss, damage or injury, cost or expense of whatsoever nature directly or indirectly caused by or resulting from or in connection with any of the following regardless of any other cause or event contributing concurrently or in any other sequence to the loss:

5.1.1 war invasion acts of foreign enemies hostilities or warlike operations (whether war be declared or not) civil war, rebellion, revolution, insurrection, civil commotion assuming the proportions of or amounting to an uprising military or usurped power; or

5.1.2 any act of terrorism.

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

This Exception also excludes loss damage bodily injury cost or expense of whatsoever nature directly or indirectly caused by or resulting from or in connection with any action taken in controlling preventing suppressing or in any way relating to 5.1.1 and/or 5.1.2 above.

If the SBIGIC allege that by reason of this exclusion any loss damage injury cost or expense is not covered by this insurance the burden of proving the contrary shall be upon the Insured.

In the event any portion of this Exception is found to be invalid or unenforceable the remainder shall remain in full force and effect.

- 5.2 any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from:
- 5.2.1 ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel;
- 5.2.2 the radioactive toxic explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.
- 5.3 any Claim arising from Hepatitis 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 in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named.
- 5.4 any Claim arising from any condition directly or indirectly caused by or associated with Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).
- 5.5 liability arising from any Occurrence happening prior to the Retroactive Date.
- 5.6 any:
- 5.6.1 Claim made against the Insured prior to the Period of Insurance;
- 5.6.2 circumstance disclosed by the Insured to the SBIGIC prior to the inception of this Policy;
- 5.6.3 circumstance disclosed by the Insured to any prior insurer; or
- 5.6.4 any Claim arising out of any Claim or circumstance of which the Insured was aware prior to the inception of this Policy and which the Insured knew, or ought reasonably to have known might give rise to a Claim or loss under this Policy.
- 5.7 any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from asbestos, asbestos fibres, asbestos dust or any materials containing asbestos.
- 5.8 any Claim which arises out of any act, error or omission outside of the terms or instructions of the Trial protocol.
6. Conditions of Compensation
- 6.1 The Research Subject shall be entitled to compensation in accordance with the following:
- 6.1.1 prior to the determination of the Research Subject's Claims or the decision of an Independent Lawyer, the Insured by way of agreement or court ruling offers the Research Subject the option of having the Research Subject Claim determined in accordance with these Conditions of Compensation; and
- 6.1.2 the Research Subject must agree within three months to the amount of compensation offered by these Conditions of Compensation.
- 6.2 In the event of 6.1.1, but no agreement between the Insured and the Research Subject after three months

the amount of compensation payable under these Conditions of Compensation shall be determined by an Independent Lawyer experienced in Medical Litigation and acting as an Arbitrator. The choice of Independent Lawyer shall be with the agreement of the SBIGIC and Research Subject and in the absence of such agreement the appointment shall be made by the Chief Justice of India and/or the equivalent body of the State or country in which the Claim is made. The arbitration shall be conducted under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996.

- 6.3 In the event of the appointment of an Independent Lawyer such person:
- 6.3.1 shall allow the parties a reasonable opportunity to present their cases with both oral and written evidence;
 - 6.3.2 shall be entitled to obtain independent expert advice;
 - 6.3.3 shall exercise any power conferred upon an Arbitrator by an Arbitration Statute or other law application in the country in which the Claim is made;
 - 6.3.4 shall otherwise determine the procedure in order to arrive at a just settlement.
- 6.4 In the event that the Insured and the Research Subject agree to be bound by the decision of the Independent Lawyer and the Research Subject accepts the amount of compensation (if any) in full and final settlement of all causes of action against the Insured or any other person in connection with the Trial, the SBIGIC will pay the reasonable costs of the Research Subject including the legal costs and expenses.
- 6.5 If the Research Subject does not accept the decision and award of the Independent Lawyer within three months, the Research Subject shall have no further entitlement pursuant to these Conditions of Compensation but shall be able to pursue such rights as the Research Subject may otherwise have.
- 6.6 If the Research Subject accepts by agreement with the Insured or the award (if any) of an Independent Lawyer then the Research Subject is bound by the following:
- 6.6.1 the Research Subject waives all rights of action against the Insured other than under these Conditions of Compensation; and
 - 6.6.2 in the event of any payment under this Policy, the Insured (and the SBIGIC) shall be subrogated to all the rights of recovery which the Research Subject may have against any third party and shall receive all help and assistance as the Insured (or the SBIGIC) may reasonably require from the Research Subject in exercising and enforcing these rights, provided that any recovery over and above any compensation paid or payable to the Research Subject (after deduction of all costs incurred in effecting such recovery) shall accrue to the Research Subject.
 - 6.6.3 the Research Subject shall sign such release or other documents as the Insured may reasonably require to give effect to Conditions 6.6.1 and 6.6.2.
- 6.7 Compensation will only be paid if, on the balance of probabilities, the Bodily Injury (including exacerbation of an existing condition) was caused by the administration to or use by the Research Subject of any drug or product involved in the Trial or was directly attributable to participation in the Trial.
- 6.8 Subject to Condition 6.11 below, compensation will not be refused solely on the basis that the Bodily Injury arose from a foreseeable adverse reaction or that the Research Subject was warned of the risk but still signed a consent form agreeing to participate in the Trial.
- 6.9 Compensation will not be paid for the failure of a drug or product under Trial to perform its intended purpose.
- 6.10 Where the Research Subject has not received the drug or product under Trial, compensation will not be

unreasonably withheld from the Research Subject if treatment or other drugs normally used in relieving any conditions for which the Research Subject was undergoing treatment were withheld or rendered ineffective by the administration of a placebo.

6.11 The amount of compensation payable shall be made with reference to the amount of damage awarded in similar cases by the courts of the country where the Trial took place and shall be commensurate with the nature and severity and persistence of the Bodily Injury. The amount of compensation may be reduced, denied or affected by the following circumstances:

6.11.1 negligence of the Research Subject or (where the Research Subject is under the age of majority) the Research Subject's parents or legal guardian;

6.11.2 the seriousness of the injury treated in the Trial and the degree of probability that adverse reactions would occur and any warning the Research Subject received;

6.11.3 the comparison of risk between established treatments and those that are used or researched in a Trial;

6.11.4 the availability and efficacy of alternative treatments which would have been available to a Research Subject had that person not agreed to participate in the Trial.

6.12 The amount of compensation shall be paid as a lump sum.

7. Conditions

7.1 Any word or expression to which a specific meaning has been attached in any part of this Policy shall bear such specific meaning wherever it may appear.

7.2 The Insured has a duty of disclosure and should the Insured fail to comply with that duty of disclosure or make a misrepresentation to the SBIGIC before this Policy was entered into and such failure was fraudulent then the SBIGIC may refuse payment of a claim and or issue notice of cancellation of this insurance. Upon receipt of this Policy the Insured agrees that it has been issued upon the truth of his declarations and representations made to the SBIGIC or any of its agents relating to this Insurance.

7.3 The terms of this Policy shall not be waived, altered or changed in any way except by endorsement issued by SBIGIC. As soon as practicable within the Period of Insurance, the Insured must notify SBIGIC of every change that materially varies any of the facts or circumstances existing at the commencement of this Policy including but not limited to any merger or acquisition of another business and material change to the services offered or the entering into voluntary or involuntary bankruptcy, receivership or liquidation.

7.4 If any part of the Deposit Premium is based on estimates furnished by the Insured, the Insured shall keep an accurate record containing all relative particulars and shall allow the SBIGIC to inspect such record. Within one month of the expiry of the Period of Insurance the Insured shall furnish such information as the SBIGIC may require. The Deposit Premium shall thereupon be adjusted and the difference paid by or allowed to the Insured, subject to the retention by the SBIGIC of any Minimum Premium.

7.5 The Insured shall take reasonable precautions to prevent any event which may give rise to liability under this Policy and to maintain all buildings, furnishings, ways, works, machinery, plant and vehicles in sound condition and, as soon as possible after discovery, cause any defect or danger to be made good or remedied and, in the meantime, shall cause such additional precautions to be taken as the circumstances may require.

7.6 The Insured shall as a condition precedent to their right to be indemnified under this Policy and regardless of any Deductible give immediate written notice to the SBIGIC of any Claim. Every Claim shall be forwarded to the SBIGIC immediately upon receipt.

7.7 No admission, offer, promise, payment or indemnity shall be made or given by or on behalf of the Insured

without the written consent of the SBIGIC. The SBIGIC shall be entitled to conduct in the name of the Insured the defence or settlement or any Claim or to prosecute in the name of the Insured for its own benefit any Claim and shall have sole discretion in the conduct of any proceedings and in the settlement of any Claim save as hereinafter provided in Conditions 7.8 and 7.9.

7.8 The Insured shall give all such assistance to deal with Claims and the conduct of legal proceedings as the SBIGIC and/or its legal advisers and consultants may require.

7.9 In connection with any Claims against the Insured, the SBIGIC may at any time pay to the Insured the Limit of Indemnity or any lesser amount for which such Claims can be settled and thereupon the SBIGIC shall relinquish the control of such Claims and be under no further liability in connection therewith except for costs and expenses which the SBIGIC have already agreed to bear in respect of matters prior to the date of such payment.

7.10 The insurance afforded by this Policy is excess over and reduced by any other valid and collectable insurance available to the Insured. Valid and collectable insurance includes any self insurance plan which would be applicable to the loss.

7.11 Premium Payment and Policy Cancellation:

7.11.1 Indemnity under this Policy is in consideration of the payment of the Premium. The Premium shall be paid in advance. In the event of non- payment, this Policy may be cancelled.

7.11.2 The SBIGIC 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 SBIGIC shall refund to the Insured a pro-rata' premium for unexpired period of Insurance.

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

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

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

7.12 Where any Claim arises from an Occurrence outside India:

7.12.1 the Insured will be required to handle the defence and investigation of any Claim where the SBIGIC are by law or circumstance prevented from indemnifying the Insured locally;

7.12.2 the SBIGIC will indemnify the Insured in India in respect of any Claim where the SBIGIC are by law or circumstance prevented from indemnifying the Insured locally.

7.13 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 SBIGIC 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.

- 7.14 In no case whatsoever shall the SBIGIC 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 SBIGIC 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.

SAMPLE

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,
		AHMEDABAD-380014 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, BHOPAL-462 011 Tel: 2578100, 2578102, 2578103, Fax: 0755-2578103 Email: insombmp@satyam.net.in
Bhubaneswar	Orissa.	62, Forst Park, BHUBANESWAR-751 009. 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, CHANDIGARH-160 017 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, CHENNAI-600 018 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 DELHI-110 002 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, HYDERABAD-500 004 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, ERNAKULAM-682 015 Tel: 2373334, 2350959, Fax:0484-2373336 Email: insuranceombudsmankochi@hclinfinet.com
Kolkata	West Bengal, Bihar, Sikkim, Jharkhand and Union Territories of Andaman and Nicobar Islands.	North British Building 29, N S Road, 3rd Floor, KOLKATTA-700 001 Tel: 22212666, 22212669, Fax:033-22212668
Lucknow	Uttar Pradesh and Uttaranchal.	Jeevan Bhavan, Phase 2, 6th floor, Nawal Kishore Road, Hazaratganj, LUCKNOW-226001 Tel: 0522-2201188, 2231330, 2231331 Fax:0522-2231310 E-mail: ioblko@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@hclinfinet.com
Guwahati	Assam, Meghalaya, Manipur, Mizoram, Arunachal Pradesh, Nagaland and Tripura.	Aquarius Bhaskar Nagar, R G Baruah Road, GUWAHATI 781 021 Tel: 2413525 EPBX:0361-2415430 Fax: 0361-2414051

INSURANCE IS THE SUBJECT MATTER OF THE SOLICITATION

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