



CLINICAL TRIALS LIABILITY INSURANCE POLICY

CLINICAL TRIALS AND/OR HUMAN VOLUNTEERS STUDIES INSURANCE POLICY

(This is a "claims made" Policy)

COVER

The Company will indemnify the **Insured** against all sums in excess of the **Deductible** that the **Insured** shall become liable to pay as **Damages** in respect of any **Claim** made by **Research Subjects** for **Bodily Injury** caused by **Serious Adverse Event** happening after the Retroactive Date stated in the Schedule within the **Policy Territory** and brought within the **Policy Jurisdiction** and arising out of participation by the **Research Subject** in any **Trial**,

Provided that

- (i) such **Claim** is first made in writing against the **Insured** during the Period of Insurance stated in the Schedule and is notified in writing to the Company during or within 30 days after the expiry of the Period of Insurance
- (ii) all **Bodily Injury** resulting or alleged to have resulted from the same **Trial** shall be considered as resulting from one **Serious Adverse Event** and having occurred during that Period of Insurance in which the first **Claim** is made against the **Insured** irrespective of the number of **Research Subjects** 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

The Company will also pay **Legal Costs** incurred with the written consent of the Company in the investigation, defence or settlement of any **Claim** covered by this **Policy**.

The Company's liability to pay **Damages** and **Legal Costs** shall not exceed the sum stated in the Schedule as the Limit of Indemnity.

DEFINITIONS

- (1) **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.
- (2) **Bodily Injury** shall mean temporary or permanent personal injury, sickness, disease or death and shall include without limitation mental injury, mental anguish, or shock.
- (3) **Claim** shall mean:
 - (a) the receipt by the **Insured** of any written or verbal demand for compensation (quantified or not) made by a **Research Subject**

against the **Insured**; or

- (b) any writ, statement of claim, summons, application or other originating legal or arbitral process, cross-claim, counterclaim or third or similar party notice served upon the **Insured**; or

PROVIDED ALWAYS THAT such **Claim** is:

- (i) first made against the **Insured** during the Period of Insurance; and
- (ii) notified in writing to the Company as required by this **Policy**; and
- (iii) in respect of **Bodily Injury** insured by this **Policy**.

- (4) **Damages** shall mean any amount that an **Insured** shall become legally liable to pay to the Research Subject (i) pursuant to Rule 122DAB of The Drugs and Cosmetics Rules (please refer Addendum 1); and/or (ii) in respect of judgments or awards rendered against an **Insured**; and/or (iii) a settlement to which the Company's prior written consent was obtained. "**Damages**" shall also mean the cost of medical treatment for in-patient hospitalisation (in case the study was being conducted on out-patient) or prolongation of hospitalisation (in case the study was being conducted on in-patient). "**Damages**" shall not mean or include the return or offset of, or damages measured by fees, charges, or commissions for services already provided or contracted to be provided; any amounts for which the **Insured** is not liable, or for which there is no legal recourse against the **Insured**.
- (5) **Deductible** shall mean the amount(s) stated in the Schedule which the **Insured** agrees to pay in respect of all **Damages** and **Legal Costs** before the Company shall be liable to make any payment.
- (6) **Ethics Committee** shall mean a committee which has been duly constituted in accordance with the rules and regulations as applicable from time to time and which has approved the **Trial** in respect of which a **Claim** is made.
- (7) The **Insured** shall mean any person or company named in the Schedule and shall include:
- (a) directors or partners whilst acting in their respective capacities for the **Insured**;
 - (b) any employee of the **Insured** (excluding **Medical Persons**) but only whilst acting within the scope of their duties;
 - (c) any past employee who acted for the **Insured**;
 - (d) **Medical Persons** who are employees of the **Insured** but only whilst acting within the scope of their duties;
 - (e) 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**, including persons on secondment from overseas countries;
 - (f) any trainee or person undergoing work experience;
 - (g) prospective employees being assessed by the Named Insured as to their suitability for employment;
 - (h) any voluntary helper;
 - (i) personal representatives of the **Insured**;
 - (j) 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**.

- (8) **Legal Costs** shall mean reasonable legal costs and expenses necessarily incurred by or on behalf of the **Insured** only with the prior

- written consent of the Company in relation to any **Serious Adverse Event** which may be the subject of indemnity under this **Policy**.
- (9) **Medical Persons** shall mean licensed physicians, doctors, medical nurses and dentists.
- (10) **Policy** means the Schedule, this policy wording, any endorsements attached to and forming a part of this Policy and the Insured's statements in the Proposal.
- (11) **Policy Jurisdiction** shall mean the jurisdiction of the country or territory stated in the Schedule within which a **Claim** must be made for indemnity to be granted by the Company subject all other terms, conditions and exclusions of this **Policy**.
- (12) **Policy Territory** shall mean the country or territory as stated in the Schedule within which **Bodily Injury** must occur for indemnity to be granted by the Company subject all other terms, conditions and exclusions of this **Policy**.
- (13) **Protocol** shall mean a written document that describes the objectives, design, methodology, statistical considerations and organisation of a **Trial**.
- (14) **Research Subject** shall mean any person participating in a **Trial**
- (15) **Serious Adverse Event** is an untoward medical occurrence during **Trial** that is associated with
- (a) adverse effects of investigational product(s);
 - (b) Violation of the approved **Protocol**, scientific misconduct or negligence by the sponsor or his representative or the investigator
 - (c) death;
 - (d) in-patient hospitalisation (in case the study was being conducted on out-patient);
 - (e) prolongation of hospitalisation (in case the study was being conducted on in-patient);
 - (f) persistent or significant disability or incapacity;
 - (g) injury to a child in-utero or a congenital anomaly or birth defect or is otherwise life threatening because of the participation of parent in **Trial**;
 - (h) any injury due to any **Trial** procedures involved in the study including adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol,

which results during the Period of Insurance in **Bodily Injury** that is neither expected nor intended and can be an accident or event including continuous or repeated injurious exposure to substantially the same general conditions.

- (16) **Trial** shall mean any clinical trial or Healthy Volunteer Study which complies with the existing statutory requirements or guidelines of the relevant person authority department or public or private body in the country in which the **Trial** occurred.

EXTENSIONS

Unless otherwise stated the following Extensions are subject always to the terms, conditions and exclusions contained in this **Policy**.

(1) NOTIFICATION OF EVENT OR CIRCUMSTANCE

If during the Period of Insurance the **Insured** gives written notice to the Company in accordance with Condition (6)(b) of any specific **Serious Adverse Event** which the Company accepts as being likely to give rise to a **Claim**, any **Claim** subsequently made against the **Insured** arising out of that **Serious Adverse Event** shall be deemed to have been first made against the **Insured** during the said Period of Insurance regardless of when such **Claim** is actually made.

(2) MANSLAUGHTER DEFENCE COSTS (ETHICS COMMITTEE)

The Company will indemnify the **Ethics Committee** or any member thereof in respect of **Legal Costs** incurred with the Company's written consent in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) as a result of manslaughter arising from any **Serious Adverse Event** which may be the subject of indemnity under this **Policy**.

PROVIDED THAT

- 1) the proceedings relate to an offence alleged to have been committed during the Period of Insurance and in the course of the Business
- 2) the Company will not provide indemnity:
 - (a) for fines or penalties of any kind;
 - (b) in respect of proceedings consequent upon
 - (i) **Bodily Injury** sustained by any employee of the **Insured** arising out of and in the course of employment by the **Insured** in the Business;
 - (ii) 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;

(3) Personal Accident Cover

This policy is extended to cover **Damages** due to personal accident to the **Research Subject** (excluding their dependants, heirs, executors, administrators and legal representatives) only if it can be attributed to **Trial**, upto the limit specified in the schedule. This cover will be a sub-limit within the overall limit of indemnity applicable to each person.

(4) Additional Insured

Sponsor of each **Trial** will be added as an Additional Insured under this policy, but only with respect to any liabilities arising from any **Trial** covered under this policy and conducted for this Additional Insured or on their behalf by the named Insured.

It is also declared and agreed that each person or party indemnified is separately indemnified in respect of claims made against any of them by **Research Subject**, subject to Company's total liability not exceeding the limits of indemnity stated in the Schedule of the Policy.

EXCLUSIONS

The Company shall not be liable for:

- (1) any consequence, whether direct or indirect, of war, invasion, act of foreign enemy, hostilities (whether war be declared or not), civil war, rebellion, revolution, insurrection, military or usurped power;

- (2) any liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from:
- (a) ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel;
 - (b) the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.
- (3) liability arising from any **Serious Adverse Event** happening prior to the Retroactive Date;
- (4) any **Claim** arising out of any **Serious Adverse Event** the circumstances of which the **Insured** were aware, or ought reasonably to have been aware, prior to the commencement of the current Period of Insurance;
- (5) liability arising from the failure of the drug or product (or any part thereof) to fulfil the purpose for which it was designed or to perform as specified, warranted or guaranteed;
- (6) any drug or product causing or failing to cure or alleviate any condition directly or indirectly caused by or associated with
- (i) Hepatitis
 - (ii) Human T-Cell Lymphotropic Virus Type iii (HTLViii) 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 shall be named
 - (iii) Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD)
- (7) notwithstanding any provision to the contrary within this **Policy** or any Endorsement thereto, any liability for loss, injury, damage, cost or expense of whatsoever nature directly or indirectly caused by, resulting from or in connection with
- (a) any **Act of Terrorism** regardless of any other cause or event contributing concurrently or in any other sequence to the loss.
 - (b) any action taken in controlling, preventing, suppressing or in any way relating to any **Act of Terrorism**.
- If the Company alleges that by reason of this exclusion, any loss, injury, damage, 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 exclusion is found to be invalid or unenforceable, the remainder shall remain in full force and effect.
- (8) liability arising from the manufacture, distribution, sale, installation, removal, use, ingestion, inhalation and or exposure to asbestos or products containing asbestos including liability resulting from asbestosis or any related disease.
- (9) any financial loss which is not directly consequent upon **Bodily Injury**.
- (10) costs incurred in the repair, reconditioning, modification, or replacement of any drug or product or any part thereof or any financial loss consequent upon the necessity for such repair, reconditioning, modification or replacement.

- (11) costs arising out of the recall of any drug or product or any part thereof.
- (12) 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 **Trial**.

CONDITIONS OF COMPENSATION

- (1) Compensation will not be solely refused on the basis that the 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**;
- (2) Compensation will not be unreasonably with-held from a **Research Subject** not receiving the drug or product under **Trial** if treatment or other drugs normally used in relieving any conditions for which the **Research Subject** was undergoing treatment were with-held or caused by the administration of a placebo;

POLICY CONDITIONS

- (1) This **Policy** and the Schedule shall be read together as one document and any word or expression to which a specific meaning has been attached in any part of this **Policy** or of the Schedule shall bear such specific meaning wherever it may appear.
- (2) By acceptance of this **Policy** the **Insured** agrees that it has been issued in reliance upon his declarations and representations made to the Company in the Proposal, which shall be the basis of this contract and is deemed to be incorporated herein.
- (3) The terms of this **Policy** shall not be waived, altered or changed in any way except by Endorsement issued by the Company to form a part of this **Policy**.
- (4) If any part of the Premium specified in the Schedule is based on estimates furnished by the **Insured**, the **Insured** shall keep an accurate record containing all relative particulars and shall allow the Company to inspect such record. Within one month of the expiry of the **Period of Insurance** the **Insured** shall furnish such information as the Company may require. The Premium shall thereupon be adjusted and the difference paid by or allowed to the **Insured** subject to the retention by the Company of any minimum Premium.
- (5) The **Insured** shall take reasonable precautions to prevent any event which may give rise to liability under this **Policy** and as soon as possible after discovery, cause such additional precautions to be taken as the circumstances may require.
- (6) The **Insured** shall, as a condition precedent to its right to be indemnified under this **Policy** and regardless of any **Deductible**, give written notice as soon as reasonably practicable and in any event within 30 days to the Company of:
 - (a) the receipt by the **Insured** of any **Claim**;
 - (b) any specific event which in the opinion of the **Insured** may give rise to a **Claim**.

Every **Claim** writ summons or process shall be forwarded to the Company immediately on receipt.

- (7) It is a condition precedent to the Company's liability that no admission offer promise payment or indemnity shall be made or given by or on behalf of the **Insured** without the prior written consent of the Company. The Company shall be entitled to conduct in the name of the **Insured** the investigation, defence or settlement of 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 (8) and (9) and the Conditions of Compensation.
- (8) The **Insured** shall assist and cooperate with the Company in the investigation and defence of all **Claims** and conduct of legal proceedings arising therefrom as the Company and/or its legal advisers and consultants may require.
- (9) Any dispute or difference arising out of or in connection with this **Policy** shall be subject to and determined in accordance with Indian law and by the Indian Courts..

(10) **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 a sole arbitrator to be appointed in writing by the parties hereto 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 arbitration shall be conducted under and in accordance with the provisions of the Indian Arbitration and Conciliation Act 1996.

It is clearly agreed and understood that no dispute or difference shall be referable to arbitration as herein before 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 and that the Indian Courts shall have sole and exclusive jurisdiction over any such action or suit.

- (11) If any **Claim** is in any manner false, dishonest or fraudulent, or is supported by any false, dishonest or fraudulent means or devices, whether by any **Insured** or anyone acting on behalf of an **Insured** or with the **Insured's** knowledge, then this **Policy** shall be void and all benefits paid or potentially payable under it shall be forfeited.
- (12) The Company shall be subrogated to all the **Insured's** rights of recovery against all persons and organisations to which the Company is or would become entitled upon making a reimbursement under this **Policy** and the **Insured** shall execute and deliver all papers required and shall do everything necessary to secure and preserve such rights, including the execution of documents necessary to enable the Company effectively to bring suit in the name of the **Insured** irrespective of whether any payment has been made under the **Policy**.

(13) **Contribution:**

If at the time of happening of any event resulting into a liability covered by this Policy, there shall be existing any other liability Insurance of any nature covering the same liability, whether effected by Insured or not, then we will pay only the rateable proportion

This policy does not cover liability which at the time of happening of an event resulting into such liability, be insured by or would, but for



existence of this policy, be insured by any other policy (but not a liability policy) or policies, except in respect of any excess beyond the amount which would have been payable under such policy/policies, had this not been effected

(14) This **Policy**:

- (a) cannot be cancelled by the Company, except in the event of non-payment of premium.
- (b) may be cancelled at any time by the **Insured** on 30 days notice to that effect being given to the Company and provided no claim has arisen during the current Period of Insurance, the **Insured** shall be entitled to the difference if any between the premium paid and the premium calculated at the Company's short period rate for the time the **Policy** had been in force based on the following table

Period	Rate
Not Exceeding	
1 week	10% of the annual rate
1 month	25% of the annual rate
2 months	35% of the annual rate
3 months	50% of the annual rate
4 months	60% of the annual rate
6 months	75% of the annual rate
8 months	85% of the annual rate
Exceeding 8 months	full annual premium

What to do in the event of a claim?

If an event happens which may give rise to a claim under this Policy you must:

1. Inform incident to us as soon as possible. You will be provided with advice on the procedure to follow. You may call _____ OR notify loss by email to OR report claim on Website OR send Letter or Fax to _____ office
2. Please supply us with all information we require to settle the claim.
3. Take all reasonable precautions to prevent further loss or damage.
4. Not negotiate, admit, repudiate or pay any claim by any person.
5. Co-operate with us fully in any action we take if we have a right to recover any money payable under this Policy from any other person.
6. If in doubt at any time please call us for advice

What you must not do in the event of a claim?

You must not:

1. admit liability if an incident occurs which is likely to result in someone claiming against you
2. make any admission of guilt or promise or offer of payment in connection with any such claim, unless we first agree in writing. This applies to you or any other person making a claim under this Policy.

Dispute Resolution

_____ will take all steps to settle your claim in accordance with policy terms and conditions. However, since the policy does not cover all eventualities, there may be disagreement between us about the Policy.

For resolution of such disputes _____ has developed an elaborate Grievance Redressal mechanism.

At your request, the claim will be considered afresh by the Grievance Committee of _____. If you are not satisfied with the decision of the Grievance Committee you may refer your case for legal advice.



ADDENDUM 1:

The Drugs and Cosmetics Rule 122DAB - FORMULA TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF CLINICAL TRIAL RELATED SERIOUS ADVERSE EVENTS (SAES) OF DEATHS OCCURRING DURING CLINICAL TRIALS