

CLINICAL TRIALS LIABILITY

Policy Wording



MAGMA HDI
Clinical Trials
General Insurance Company Ltd.

Important Notice to the Insured

Please read this policy carefully to ensure that it is in accordance with your requirements and that you understand its terms and conditions. The Company should be contacted immediately if any correction is necessary

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 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 of the **Insured** as stated in the Schedule.

Provided that

- (i) such **Claim** is first made in writing against the **Insured** during any **Period of Insurance** and is notified to the Company during or within 30 days after expiry of the same **Period of Insurance**
- (ii) all **Bodily Injury** resulting or alleged to have resulted from the same **Trial** shall be considered as resulting from one **Occurrence** and having occurred during that **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 **Claim** or **Claims** being made against the **Insured** at some future date
- (iii) the **Insured** has offered and the **Research Subject** has agreed to abide by the Conditions of Compensation and the **Research Subject** has agreed and accepted the amount of Compensation determined by an **Independent Lawyer**

The Company will also pay **Legal Costs** in addition to the Limits of Indemnity

DEFINITIONS

- (1) The **Insured** shall mean any person or company named in the Schedule and at the request of the **Insured** shall include
 - (a) director partners whilst acting in their respective capacities for the **Insured**
 - (b) any employee of the **Insured** including **Medical Persons** but only whilst acting within the scope of their duties
 - (c) 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
 - (d) any sub-contractor doctor consultant physician hospital or contract research organization or nurse who will be performing work for the **Insured** in respect of a **Trial** covered by this Policy
 - (e) any Ethics Committee or its members that has approved a Trial which is the subject of this Policybut on in respect of Claims arising out of a Trial covered by this Policy
- (2) **Bodily Injury** shall mean personal injury sickness disease or death and shall include but not by way of limitation mental injury metal anguish shock
- (3) **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**
- (4) **Legal Costs** shall mean all the costs and expenses (including any fees or disbursements of any **Independent lawyer / experts / loss adjusters**) incurred by or on behalf of the **Insured** with the written consent of the Company in relations to any **Occurrences** which may be the subject of Indemnity under this Policy
- (5) **Medical Persons** shall mean Licensed Physicians Doctors Medical Nurses and Dentists

- (6) **Deductible** shall mean the amount(s) which the **Insured** agrees to pay in respect of all damages compensation and claimant's costs and expenses before the Company shall be liable to make any payment
- (7) **Claim** shall mean a written demand made against the **Insured** for money or services in respect of **Bodily Injury** insured by this Policy
- (8) **Research Subject** shall mean any person participating in a **Trial** including their dependants heirs executors administrators and legal representatives
- (9) **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
- (10) **Independent Lawyer** shall mean a judge retired judge barrister or solicitor

EXTENSIONS

Unless otherwise stated the following Extensions are subject always to the terms conditions and exceptions contained in this Policy

(1) NOTIFICATION OF EVENT OR CIRCUMSTANCE

If during the **Period of Insurance** the **Insured** shall give written notice to the Company in accordance with Condition (6)(b) of any specific event or circumstance which the Company accepts as being likely to give rise to a **Claim** and **Claim** subsequently made against the **Insured** arising out of that event or circumstance 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) DISCOVERY

In the event of the Company –

- (a) cancelling or refusing to renew this Policy for any reason other than
 - (i) any act of fraud or dishonesty by the **Insured** or
 - (ii) non-disclosure of a material fact by the **Insured** in connection with the issuance of this Policy or
- (b) renewing or replacing this Policy on different terms from those contained herein or
- (c) increasing the premium by 300% or more upon renewal

The Company will indemnify the **Insured** subject to the terms conditions and limitations of the Policy in respect of any **Claim** which is first made in writing against the **Insured** and notified to the Company during a period of 12 months immediately following the effective date of such cancellation or non-renewal as if the **Claim** had been made against the **Insured** and notified to the Company during the **Period of Insurance** except where otherwise stated in proviso (v) below;

Provided always that;

- (i) the Extension will not apply where indemnity is provided by any other insurance or by virtue of Extension (1)

- (ii) the total amount payable for all **Claims** made during the **Period of Insurance** including those **Claims** deemed to have been so made by virtue of the terms of this Extension shall not exceed the Limits of Indemnity as stated in the Schedule
- (iii) in the event of (b) above the indemnity afforded by this Extension shall apply only in respect of the different terms imposed
- (iv) such **Claim** result from **Bodily Injury** happening on or after the Retroactive Date and prior to the effective date of such cancellation or non-renewal
- (v) any such **Claims** in connection with an Occurrence which has given rise to any other **claim** first made and notified during any **Period of Insurance** shall be deemed to have been made and notified on the on the date the first of those **Claims** was made

In the event of the **Insured** cancelling or not renewing this **Policy** after complying with all the terms and conditions thereof including the payment of all premiums when due the Company will indemnify the **Insured** subject to all the terms conditions and limitations of the Policy in respect of any **Claim** which is first made in writing against the **Insured** and notified to the Company during a period of six months immediately following the effective date of such cancellation or non-renewal as if the **Claim** had been made against the **Insured** and notified to the Company during the **Period of Insurance** subject to the provisos stated above

The fact that the indemnity afforded by this Policy may be extended shall not reinstate or in any way increase the Limits of Indemnify set forth in the Schedule or extend the **Period of Insurance**.

MAGMA HDI EXCEPTIONS

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 legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from
 - (a) ionizing 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) 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 (LAV0 or the mutants derivatives or variation 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
- (4) liability arising from any **Occurrence** happening prior to the Retroactive Date
- (5) any **Claim** arising out of an **Occurrence** the circumstances of which the **Insured** were aware prior to the inception of this Policy
- (6) damages to health and/or worsening or already existing damage to health which might have occurred or continued even if the **Insured** would not have taken part in the clinical tests;

- (7) **Genetic damages;**
- (8) damage to health, which has been caused by any actions of the **Insured** which were contradictory to explicit instructions given him by the person in charge of the clinical testing;
- (9) Claims arising out of any **Medical Malpractice** of any **Medical Person**
- (10) Any **Claim** arising from the failure by the Insured to follow the protocol specified in the schedule of insurance including any amendments to this protocol providing that the Insurer has received prior written notice of the amendment in accordance with the policy conditions.
- (11) any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from any substance known to have harmful side effects including but not limited to:
 - a. Diethylstilbestrol
 - b. Stilbestrol / D.E.S.
 - c. Primodos
 - d. Amenorone-Forte
 - e. Swine-Flu Vaccine
 - f. Clindamycin
 - g. Lincomycin
 - h. Debendox
 - i. Halogenated 8 Hydroxy Quinolimes
 - j. Phen / Fen

CONDITIONS OF COMPENSATION

1. The **Research Subject** shall be entitled to compensation in accordance with the following:
 - (a) 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
 - (b) the **Research Subject** must agree within three months to the amount of compensation offered by the conditions of compensation
2. In the event of (a) and (b) in number 1 above 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 Company and **Research Subject** and in the absence of such agreement the appointment shall be made by the President for the time being of the Law Society of India and/or the equivalent body of the country in which the **Claim** is made
3. In the event of the appointment of an **Independent Lawyer** such person:-
 - (a) shall allow the parties a reasonable opportunity to present their causes with both oral and written evidence.
 - (b) shall be entitled to obtain independent expert advice
 - (c) 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
 - (c) shall otherwise determine the procedure in order to arrive at a just settlement
 - (d) shall otherwise determine the procedure in order to arrive at a just settlement

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** accept 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 Company will pay the reasonable costs of the **Research Subject** including the **Legal Costs** and expenses
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. 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:-
 - (a) the **Research Subject** waives all rights of action against the **Insured** other than under these Conditions of Compensation and
 - (b) In the event of any payment under this Policy the **Insured** (and thus the Company) shall be subrogated to all the rights of recovery thereof which the **Research Subject** may have against any third party and shall receive all help and assistance as the **Insured** (or the Company) 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**
 - (c) the **Research Subject** shall sign such release or other documents as the **Insured** may reasonably require to give effect to (a) and (b) of Condition 6 above
7. Compensation will only be paid if on the balance of probabilities the 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**
8. Subject to Condition (11) below, 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**
9. Compensation will not be paid for the failure of a drug or product under **Trial** to perform its intended purpose
10. 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
11. The amount of compensation payable shall be made with reference to the amount of damage awarded in similar cases by the court of the country where the **Trial** took place and commensurate with the nature and severity and persistence of the injury

The amount of compensation may be reduced denied or affected by the following circumstances: –

- (a) negligence of the **Research Subject** or (where the **Research Subject** is under the age of majority) the **Research Subject's** parents or legal guardian
- (b) 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
- (c) the comparison of risk between established treatments and those that are used as researched in a **Trial**
- (d) 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**

12. The amount of compensation shall be paid as a lump sum
13. In the event of any change of the proposed in the protocol the **Insured** has to
 - 13.1 notify the **Insurer** of any proposed changes to the protocol within five (5) days and in writing including full particulars of the nature and extend of the proposed changes in the protocol

and

- 13.2 notify the **Insurer** of any actual changes to the protocol within five (5) days and in writing of any actual change in the protocol including full particulars of the nature and extend of the actual changes in the protocol
14. No claim shall be payable unless the insured claims payment by serving legal process on the company within 6 month of the rejection of the claim in writing and pursues such proceedings to finality
15. In the event of any material alteration in the risk the **Insurer** reserves the right to alter the terms and conditions of the policy This does not exclude the right to cancel this agreement

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 on 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 the truth of his declarations and representations made to the Company or any of its agents relating to this Insurance
- 3) The terms of this Policy shall not be waived altered or changed in any way except by Memoranda issued by the Company to form a part of this Policy
- 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 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 Deposit 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 Occurrence 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 their right to be indemnified under the Policy and regardless of any Deductible give immediate written notice to the Company of
 - (a) the receipt by the **Insured** of any **Claim**
 - (b) any specific event or circumstance 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) 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 Company. The Company shall be entitled to conduct in the name of the **Insured** the defence or settlement of 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 (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. The choice of Counsel is to be agreed by the **Insured** and the Company but failing agreement the Company alone shall be entitled to nominate the Counsel of their choice
- 9) In connection with any **Claims** against the **Insured** the Company may at any time pay to the Insured the Limit of Indemnity or any less amount for which such **Claims** can be settled and thereupon the Company shall relinquish the control of such **Claims** to the **Insured** and be under no further liability in connection therewith except for costs and expenses which the Company, have already agreed to bear in respect of matters prior to the date of such payment
- 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 include any self insurance plan which would be applicable to the loss
- 11) The Company or the **Insured** may cancel this Policy by giving thirty days' notice in writing to the other party at its Last known address. Such notice, if given by the Company, shall be deemed sufficiently given if sent by registered post with acknowledgement due to the Insured at the address last registered in the Company's books and shall be deemed to have been received by the Insured at the time when the same would be delivered.

If the policy is cancelled by the Company the **Insured** shall entitled to a refund a rateable proportion of the premium for the unexpired portion of the policy. If the policy is cancelled by the **Insured**, the **Insured** shall only be entitled to a refund after adjustment of premium in accordance with the Company's usual short period scale mentioned hereunder provided that no claim has been made in the then current Period of Insurance.

Short Period Rates

Period for which policy has remained in force as on date of cancellation	% Retention by the Company
Less than 30 days	25% of Annual Premium
Exceeding 30 days and upto 90 days	50% of Annual Premium
Exceeding 90 days and upto 180 days	75% of Annual Premium
Above 180 days	Full Annual Premium – No Refund is allowed
