

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 an **Occurrence** happening after the Retroactive Date stated in the Schedule within the **Policy Territory** and brought within the **Policy Jurisdiction** 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 the Period of Insurance stated in the Schedule and is notified in writing to the Company during 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 **Occurrence** 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
- (iii) the **Insured** has offered and the **Research Subject** has agreed to abide by the Conditions of Compensation and the **Research Subject** has agreed to accepted the amount of compensation determined as per the Conditions of Compensation by an **Independent Lawyer**

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 the Conditions of Compensations; or (ii) in respect of judgments or awards rendered against an **Insured**; or (iii) a settlement to which the Company's prior written consent was obtained. "**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) **Independent Lawyer** shall mean a retired judge of the Supreme Court of India or of a High Court or an advocate or solicitor licensed to practice law in India.
- (8) The **Insured** shall mean any person or company named in the Schedule and, at the request of the **Insured**, 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** and who agrees to be bound by the terms of this Policy;
 - (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**;
- (f) 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** and provided always that items (d), (e) and (f) are included only subject to the prior written agreement of the Company.

- (9) **Legal Costs** shall mean reasonable legal costs and expenses (including any fees or disbursements of any **Independent Lawyer**) necessarily incurred by or on behalf of the **Insured** only with the prior written consent of the Company in relation to any **Occurrence** which may be the subject of indemnity under this **Policy**.
- (10) **Medical Persons** shall mean licensed physicians, doctors, medical nurses and dentists.
- (11) **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** that is neither expected nor intended.
- (12) **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.
- (13) **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**.
- (14) **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**.
- (15) **Research Subject** shall mean any person participating in a **Trial** including their dependants, heirs, executors, administrators and legal representatives.
- (16) **Trial** shall mean any clinical trial or Healthy Volunteer Study which 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 **Occurrence** which the Company accepts as being likely to give rise to a **Claim**, any **Claim** subsequently made against the **Insured** arising out of that **Occurrence** 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 **Occurrence** 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) 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;

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 **Occurrence** happening prior to the Retroactive Date;
- (4) any **Claim** arising out of an **Occurrence** 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) (a) claims arising from the production, sale or provision of the following:-

<ol style="list-style-type: none"> 1) Atomoxetine 2) Blood Borne Pathogens 3) Canthaxanthin 4) Cerivastatin and/or any other statins and/or fibrates 5) Contraceptives (including birth control pills) fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy 6) Cisapride 7) Cox-2 Inhibitors 8) Danthron 9) Debendox 10) Dexfenfluramine (Redux) 11) Dicyclomine when given to children under 4 years of age 12) Diethylstilbestrol 13) Dioxins 14) Doxazosin 15) Duloxetine 16) Ephedrine Ma Huang Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder Epitonin or any derivative thereof 17) Fenfluramine (Pondimin) 18) Fluoxetine 19) Germanium 	<ol style="list-style-type: none"> 20) Halogenated 8 & Hydroxy Quinolines 21) Hydroquinone 22) Infliximab 23) Isotretinoin (Accutane) 24) Methylphenidate 25) Nefazodone 26) Pertussis Vaccine 27) Phenfluramine (Fen-Phen) 28) Phenylpropanolamine (PPA) 29) Primodos / Amenorone Forte 30) Retinoic Acid 31) Rosiglitazone 32) Sertraline 33) Skin whitening or lightening agents 34) Selective Serotonin Reuptake Inhibitors 35) Swine-Flu Vaccine 36) Terbinafine 37) Thalidomide 38) Tretinoin (retinoic acid or its salts) 39) Tryptophan 40) Paroxetine 41) Pioglitazone 42) Lotronex 43) Thimersol or Thimersal 44) Troglitazone
--	---
- (b) any drug or product causing or failing to cure or alleviate any condition directly or indirectly caused by or associated with



RAHEJA QBE GENERAL INSURANCE CO. LTD.

- (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) liability for any loss, damage, demand, claim, cost, expense, suit, defence or other obligation of any kind or description directly or indirectly arising from or relating to Mould. This exclusion applies to any potential, alleged, or actual liabilities and agreements to defend or indemnify, whether for injury, damage, medical expense or otherwise. For the purposes of this exclusion the word "Mould" shall be deemed to include but not be limited to the following:
- mould or fungi or its spores, bacteria, yeasts, mildew, algae, mycotoxins or any other metabolic products, enzymes or protein secreted by the above whether toxic or otherwise.
- (10) any financial loss which is not directly consequent upon **Bodily Injury**.
- (11) 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.

- (12) costs arising out of the recall of any drug or product or any part thereof.
- (13) compensation of any kind or description (a) to research participants receiving placebo in consideration of such placebo's failure to provide therapeutic benefit and (b) in relation to the natural progression of an underlying disease.

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** by a court or tribunal or the decision of an **Independent Lawyer**, the **Insured** by way of agreement or undertaking to the court or tribunal offers to have the **Research Subject's Claim** determined in accordance with these Conditions of Compensation; and
 - (b) within three months of such offer by way of agreement or undertaking, the **Research Subject** agrees to accept the amount of compensation offered by the Conditions of Compensation.
- (2) In the event condition 1) above is fulfilled, but no agreement is reached between the **Insured** and the **Research Subject** within three months regarding the amount of compensation offered by these Conditions of Compensation, then 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 under the relevant arbitration statute applicable in the jurisdiction where the Claim is made. The **Independent Lawyer** shall be appointed with the agreement of the Company and **Research Subject** and in the absence of such agreement within 30 days from the end of the three months referred to at 1) (b) above, the appointment shall be made by the President for the time being of the Law Society of England and Wales 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 cases 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 the relevant arbitration statute or other law application in the country in which the **Claim** is made;
 - (d) shall otherwise determine the procedure in order to arrive at a just settlement;
 - (e) shall give due regard to and follow the conditions of compensation set out in these Conditions of Compensation, provided that if any such conditions conflict with the



RAHEJA QBE GENERAL INSURANCE CO. LTD.

applicable law of the jurisdiction in which the **Claim** is made, then the latter shall prevail.

- (4) The **Insured** and the **Research Subject** agree to be bound by the decision of the **Independent Lawyer** and the **Research Subject** agrees to 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**. In such event, the Company shall also pay any **Legal Costs** awarded by the **Independent Lawyer** to the **Research Subject**.
- (5) If the **Research Subject** accepts the compensation by agreement with the **Insured** under these Conditions of Compensation or if an **Independent Lawyer** is appointed to determine such compensation (if any) then the **Research Subject** agrees to be 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 to the Research Subject under the Conditions of Compensation, of 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; and**
 - (c) the **Research Subject** shall sign such release or other documents as the **Insured** (or the Company) may reasonably require to give effect to (a) and (b) of Condition 5 above.
- (6) 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**;
- (7) Subject to Condition (10) 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**;
- (8) Compensation will not be paid for the failure of a drug or product under **Trial** to perform its intended purpose;
- (9) Compensation will not be unreasonably with-held from a **Research Subject** not receiving



RAHEJA QBE GENERAL INSURANCE CO. LTD.

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;

- (10) 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 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 or 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**.
- (11) The amount of compensation shall be paid as a lump sum.

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



RAHEJA QBE GENERAL INSURANCE CO. LTD.

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. The choice of **Independent Lawyer** is to be agreed by the **Insured** and the Company but failing agreement the Company alone shall be entitled to nominate the **Independent Lawyer** 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 includes any self insurance plan which would be applicable to the loss.
- (11) It is hereby warranted that the **Insured** shall maintain full rights of recourse against manufacturers and licensors of drugs and products.
- (12) 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..
- (13) **Arbitration**

If any dispute or difference shall arise as to the quantum to be paid under this Policy



RAHEJA QBE GENERAL INSURANCE CO. LTD.

(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.

- (14) 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.
- (15) 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**.
- (16) This **Policy** may be cancelled at any time:
 - (a) by the Company on 30 days notice to that effect being sent in writing to the **Insured's** last known address and in such event the Company will return a pro rata portion of the premium for the unexpired part of the Period of Insurance;
 - (b) 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.