HDFC ERGO General Insurance Company Limited

SER- CLINICAL TRIALS INSURANCE POLICY
(This is a claims made policy)

COMPENSATION INSURANCE FOR CLINICAL TRIALS AND/OR HUMAN VOLUTEERS STUDIES

Producer :

SER CLINICAL TRIAL POLICY

Insurance Contract

Please read the entire policy carefully. The terms and conditions of this insurance include the various sections of this insurance contract: Insuring Clauses; Limit of Liability; Exclusions; Clinical Trials Compensation Guidelines; Definitions; Conditions and Extensions, as well as any Endorsements and Schedules made a part of this insurance.
Words and phrases that appear in **bold** print have special meanings and are defined in the Definitions section of this insurance contract.

Throughout this insurance contract the words "you" and "your" refer to the Named **Insured** shown in the Schedule and other persons or organizations qualifying as a named **insured** under this insurance contract. The words "we," "us", "our" and "Company" refer to HDFC ERGO General Insurance Company Limited.

THIS INSURANCE PROVIDES CLAIMS-MADE COVERAGE. EXCEPT AS OTHERWISE PROVIDED, SUCH COVERAGE APPLIES ONLY TO CLAIMS THAT ARISE OUT OF A RESEARCH SUBJECT'S PARTICIPATION IN A TRIAL COMMENCING WITHIN THE POLICY PERIOD, WITHIN 12 MONTHS AFTER THE EXPIRATION OF THE TRIAL OR ANY EXTENDED REPORTING PERIOD, IF APPLICABLE, AND BOTH FIRST MADE AGAINST THE **INSURED** AND REPORTED TO US IN WRITING DURING THE TRIAL PERIOD, 12 MONTHS AFTER THE EXPIRATION OF THE TRIAL OR ANY EXTENDED REPORTING PERIOD, IF APPLICABLE.

LEGAL COSTS WILL REDUCE THE LIMIT OF LIABILITY.

Insuring Clauses

Section A Settlement with Mediation

Subject to the Limit of Liability in excess of the Deductible the Company will indemnify the **Insured** for all sums which the **Insured** shall pay to a **research subject** as a result of a settlement agreement reached between the **research subject** and the Insured in the event of a **claim** by the **research subject** against the **Insured** arising out of the **research subject's** participation in a **trial** commencing within the Policy Period or where applicable within any Retroactive Date shown in the Trial Master Schedule. Included are costs and expenses for the arbitration.

The settlement should either be approved by the Company in writing or be the result of an assessment by an **independent lawyer** following the clinical trial Compensation Guidelines attached to this policy. Details of the procedure are laid down in the Clinical Trial Compensation Guidelines which form an integral part of this policy wording.

If the **Insured** and **research subject** are unable to reach agreement pursuant to Section A then alternatively the Company will indemnify the **Insured** as follows:

Section B Legal Liability

Subject to the Limit of Liability in excess of the Deductible the Company will indemnify the **Insured** for all sums including **legal costs** which the **Insured** shall be legally liable to pay as damages and compensation awarded by a court for **property damage** as well as **bodily injury, personal injury** and **advertising injury** caused to a **research subject** by the **research subject's** participation in a **trial** commencing within the Policy Period, or where applicable within any Retroactive Date shown in the Trial Master Schedule.

In respect of Section A and B above:

Coverage applies only if :

a. exposure to **drug, medical** device or material upon or within human beings during such trial, did not first happen before the beginning of the **trial period,** or where applicable any Retroactive Date shown in the Trial Master Schedule**;** and

b. a **research subject**'s claim for the **bodily injury** or **property damage** is both first made against an **insured** and reported to us in writing during:
   i) the **trial period**; or
   ii) within 12 months after expiry of that **trial period** or
   iii) any Extended Reporting Period you request before the **trial** has started and we agree to provide by an endorsement for an additional premium.

c. the **Insured** shall give written notice to the Company as soon as possible after becoming aware of any circumstances which might reasonably be expected to produce a **claim** against the **Insured.** Any **claim** arising from such circumstances shall be deemed to have been made in the **trial period** in which such notice has been given.

Provided that any **claim** resulting or alleged to have resulted from the same **trial** will be deemed to have been made at the time the first **claim** was notified to the Company.

Section C Medical payments Coverage

In addition to the above, subject to the applicable **medical payments** for Trials Limit of Indemnity in excess of the Deductible, the Company will pay for **medical payments** in respect of each **research subject** who sustains **bodily injury** arising out of their participation in a **trial** when such injury was incurred during the **Trial Period** and reported to the Company within one year from the date of sustaining the **bodily injury.**

The **research subject** must submit to medical examination, at the Company's expense and by physicians of its choice, as often as is reasonably required.

This section excludes **medical payments** for **bodily injury** to any person taking part in athletic pursuits concurrently with a **trial.**

Limit of Liability

The total aggregate liability of the Company for all damages and compensation payable out of a series of claims whether agreed or assessed in accordance with the Compensation Conditions under Insuring Clause Section A or for Legal Liability under Insuring Clause B shall not exceed the Limit of Liability stated in the schedule for the Policy Period or stated for each trial in the Trial Master Schedule, as applicable, irrespective of the number of claims made or the number of Insureds claiming under this insurance.

The payment by the Company of any sum under this insurance shall reduce the available Limit of Liability in respect of any other claim, whether against the same Insured or against any other person falling within the definition of the Insured.

The liability of the Company for all damages and compensation payable arising from the **Insured**'s occupation of the premises in which the **trial** is being conducted shall be limited to the Limit of Liability stated in the Schedule for any one **claim** or series of **claim**s arising from any **occurrence.**

All **legal costs** will reduce the limit of liability

In respect of Section A, B and C above:

Coverage is subject to the following prerequisites:

1. Compliance with the Declaration of Helsinki developed by the World Medical Association (Ethical Principles for Medical Research Involving Human Subjects) in the latest version

2. Compliance with the Good Clinical Practice (GCP) provided by the International Conference on Harmonisation (ICH) in the latest version

3. Compliance with the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP)

4. Compliance with the current Good Manufacturing Practice (GMP) applied by the pharmaceutical regulators in the country where the study is conducted if active pharmaceutical ingredients are applied.

5. Presentation of the Written Study Protocol prior to the start of the **trial**. If the **trial** has already started, all necessary information and a statement that no claim has occurred so far or all information about occurred claims has to be provided to the Company.

6. The risks and benefits as well as the experimental character of the tests are explained in that way to the **research subject**s that no liability due to lack of or insufficient information may arise.

7. Written Informed Consent in the language of the **research subject**, signed by each **research subject.**

8. Consent of **human research ethics committee** to be given before the start of the **trial**

9. National Regulations are followed – responsibility for compliance lies with the sponsor.

Exclusions

The indemnity provided does not apply to liability arising from:

1 any **claim** arising from viral Hepatitis or any condition directly or indirectly caused by or associated with Human Immunodeficiency Virus (HIV I) or (HIV II), Human T-Cell Lymphotropic Virus Type 1 (HTLV I) to 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 however it may be named.

However, this exclusion does not apply if the contamination can be analyzed in the retained sample of the administered biological active pharmaceutical ingredient.

2 any condition directly or indirectly caused by or associated with Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD)

3 any circumstances which are either:-

a. known to the **Insured** at the inception of this Policy or

b. likely to give rise to a **claim** against which the **Insured** would otherwise be entitled to be indemnified under more specific insurance or

c. have been notified under any other insurance attaching prior to the inception of the Policy.

4 any **claim** arising out of any **trial** commencing prior to the Retroactive Date.

5 **bodily injury** sustained by any **employee** arising out of and in the course of their employment or engagement by the **Insured.** This exclusion shall not apply where an **employee** is voluntarily acting as a **research subject.**

6 **bodily injury** sustained by a **research subject** which was reasonably foreseeable. This exclusion shall not apply to **bodily injury**:

a. which is intended to result from reasonable use of a **drug** or **medical device** within or upon human beings during a **trial** or

b. which can be expected, from the standpoint of a reasonable professional conducting a **trial**, to result from reasonable use of a **drug** or device within or upon human being during a **trial**

7 the insolvency or bankruptcy of the **Insured**

8 loss of or damage to the **Insured**'s Product(s) and costs or removal, recall, alteration, replacement or reinstatement necessitated by any **defect** (suspected or known) or the unsuitability for the intended purpose.

9 punitive or exemplary damages and statutory awards of multiples of compensatory damages (i.e. treble damages).

10 a) **bodily injury, property damage, advertising injury, personal injury** or **denial of access** arising out of the actual, alleged or threatened contaminative, pathogenic, toxic or other hazardous properties of **asbestos.**

b) loss, cost or expense arising out of any :

i. request, demand, order or regulatory or statutory requirement that any **Insured** or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of **asbestos** ; or

ii. **Claim** or proceeding by or on behalf of a governmental authority or others for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of **asbestos.**

11 any claim, loss or damage directly or indirectly occasioned by , happening through or in consequence of terrorism, war, invasion,

acts of foreign enemies, hostilities (whether war be declared or not), civil war, rebellion, revolution, insurrection, military or usurped power or confiscation or naturalization or requisition or destruction of or damage to property by or under the order of any government or public or local authority;

12 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

This exclusion shall not exclude any claim directly relating to the therapeutic use of radioactivity;

13 any claim arising out of the continued use of the **drug**, treatment or product under **trial** after the Trial has been completed and after the **drug**, product or treatment has been licensed in accordance with the statutory and regulatory requirements of the country in which the Trial took place;

14 any claim arising out of or in any way connected with the alleged worsening of existing conditions or **Bodily injury** or new symptoms or new **bodily injury** of the **Research Subject** discontinuing existing treatment or medications for the purpose of participating in the Trial;

15 any claim connected with or in consequence of any service rendered by the Insured under the influence of intoxicants, narcotics or other drugs affecting neurocognitive competence.

16 any claim arising out of or in any way connected with any **bodily injury** to any baby or child under the age of two years. This exclusion does not apply to a **trial** that has been described to us by you in the application for this insurance, to the extent that we have agreed to provide coverage in connection with such **trial**

17 any claim connected to or in consequence of any damage to or change in any **Research Subject**'s DNA or any therapy or treatment influencing **Research Subject**'s DNA. This exclusion does not apply to a **trial** that has been described to us by you in the application for this insurance, to the extent that we have agreed to provide coverage in connection with such **trial**

18 any claim based upon, attributable to or in any way connected with the failure of a drug, device or procedure to perform its intended purpose or function in the course of the trial;

19 any claim arising from lack of information or insufficient information;

20 any claim arising out of or in any way connected with any Trial undertaken without the approval of **Human research ethics committee**

Clinical Trials Compensation Guidelines

1 The **Research Subject** may be entitled to compensation in accordance with the following

(a) prior to resorting to legal process to determine the **research subject**'s **claim** the **Insured** offers the **research subject** the option of having the **claim** determined with these Guidelines and

(b) the **research subject** agrees in writing within three months of the offer above the **claim** be determined in accordance with these conditions.

2 In the event of no agreement resulting between the **Insured** and the **research subject** on the amount of compensation payable then the amount of compensation (if any) 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 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 an Arbitration Statute or other law applicable in the country in which the **Claim** is made

(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 Claimant 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 Company will pay the reasonable costs of the Claimant 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 Compensation Guidelines 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 any **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 Compensation Guidelines 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 refused solely 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 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

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 **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

Definitions

Advertising Injury

Advertising injury means injury arising solely out of one or more of the following offences committed in the course of advertising the **Insured**'s **products** or services:

(a) Oral or written publication of material that slanders a person or organization or disparages a person's or organization's goods or services;
(b) Oral or written publication of material that violates a person's right of privacy;
(c) Misappropriation of advertising ideas or styles of doing business
(d) Infringements of copyrighted advertising materials, titles or slogans

Asbestos

Asbestos means **asbestos** in any form, including its presence or use in any alloy, by-product or other material or waste. Waste includes materials to be recycled, reconditioned or reclaimed.

Bodily Injury

Bodily Injury means a serious adverse effect of physical injury, sickness, or disease sustained by a person and, if arising out of the foregoing, mental anguish, mental injury, shock, humiliation or death at any time. **Bodily Injury** includes physical injury, sickness, or disease arising out of the provision of medical services irrespective of whether such provision relates to emergency relief.

Claim means a judgement, compensation request, arbitration award or other demand for money.

Defect means an actual harmful condition which:

(a) is not intended by an **Insured ;**
(b) a reasonable person in the circumstances of the **Insured** would not expect;
(c) arises out of the conduct of any **Insured** or a person or organization acting on behalf of any **Insured** ; and
(d) causes, or presents a substantial likelihood of causing **bodily injury** or **Property Damage**

Defect does not include any actual, alleged or threatened condition arising out of malicious:

(a) alteration or
(b) **Contamination** of the **Insured**'s **products**

Drug means a biologic or synthetic article intended for use:

(a) In the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in human beings and which affects the structure or any function of the human body; or

(b) As a component of any article described in paragraph A. above.

Drug does not include any **medical device** or food.

Employee means:

- any person(s) employed by the **Insured** under a contract of service or apprenticeship;
- labour masters and persons supplied by them;
- persons employed by labour only sub-contractors;
- person offering their services on a labour only basis;
- persons engaged in work experience manpower services or similar schemes;
- self-employed persons and voluntary workers; or
- any person(s) supplied to or hired in or borrowed by the **Insured**.

Human research ethics committee means:

- an ethics committee; or
- an independent board, committee, group or similar Organization not related to or dependent in any way to the **Insured.**

constituted, designated, directed or requested by an institution or other person or Organization to review a **trial**, including any:

- approval; or

- periodic review;of any such **trial.**

Independent lawyer

Independent lawyer means a judge, retired judge, barrister or solicitor with experience of medical negligence litigation.

Insured

Insured in addition to the named **Insured** in the insuring agreement the **Insured** shall also include at the request of the named **Insured**

(a) any person who was, is, or may become during the Policy Period an officer. principal, partner, trustee or member of board of governors of the named **Insured.**

(b) any **employee** or past **employee** who acted for the named **Insured** on the condition that they will subject to the policy terms and conditions.

(c) any sub contractor, doctor or consultant, contract research organizations or nurse who works for the named **Insured,** pursuant to a written contract or agreement between the **Insured** and such persons or organizations,

However,

i) cover will only apply in respect of **claims** made against them whilst working within the terms of the protocol agreed with the named **Insured**.

ii) no such person or organization is an **insured** with respect to any:

- assumption of liability by them in a contract or agreement. This limitation does not apply to the liability for damages for injury or damage, to which this insurance applies, that the person or organization would have in the absence of such contract or agreement.
- representation or warranty unauthorised by you.
- chemical or physical change in **Insured**'s **product** made intentionally by the person or organization.
- damages arising out of their fault.
- reckless or willful violation of any law or regulation.

Further, no person or organization from whom **Insured** have acquired the **product**, or any container, ingredient or part entering into, accompanying or containing **Insured**'s **product**, is an **insured** under this provision

(d) the **Human research ethics committee**, its individual members that approved a **trial** which is the subject of that insurance but only in respect of **claims** arising out of **trial** covered by this section.

(e) organization that are a **subsidiary** of the **Insured** at commencement of the Policy Period.

Legal costs

Legal costs means;

(a) claimants costs and expenses;

(b) other costs and expenses, including appeal costs incurred with the written consent of the Company, in respect of a **claim** against the **Insured** to which the indemnity expressed in this coverage applies;

(c) fees for legal services for:

i) representation at any Coroner's Court of Fatal Accident Enquiry (or other Local equivalent)

ii) defence proceedings in any Court of Summary Jurisdiction (or other local equivalent);

iii) the defence of any criminal proceedings brought or an appeal against conviction arising from such proceedings; or

iv) in respect of breach of any consumer legislation;

v) defence proceedings being taken against the **Insured** or any **Employee** or director of the **Insured**.

Medical device

Medical device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory:

- recognized as such in the official National Formulary, the official Indian Pharmacopoeia or any supplement to any of them;
- intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in human beings; or
- intended to affect the structure or any function of the human body;
- which does not achieve its primary intended purposes through chemical action within or upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Medical device does not include any **drug** or food.

Medical payments

Medical payments means reasonable expenses for:

- first aid administered at the time of the **bodily injury**

- necessary medical, surgical, x-ray and dental services, including prosthetic devices;
- and necessary ambulance, hospital professional, nursing and funeral expenses.

Occurrence

Occurrence means an accident, including continuous or repeated exposure to substantially the same general harmful conditions which results in **bodily injury** or **Property Damage.**

Personal injury (injury other than bodily injury)

Personal injury meaning injury arising out of one or more of the following offences committed during the Policy Period:

(a) false arrest restraint detention or imprisonment
(b) malicious prosecution
(c) Wrongful entry eviction or other invasion of the right of private occupancy
(d) invasion of the right of privacy of injurious falsehood or defamation of character or publication or utterance of other defamatory or disparaging material
(e) nuisance or trespass or diminution of or interference with any easement right of air or light or water or way easement or quasi easement or other environmental right or any like cause.
(f) obstruction loss of amenities stoppage of traffic.

Products

Products means any goods (including all material packaging container labels and instructions) sold, supplied, altered, constructed, handled, serviced, repaired, treated, tested, installed, erected, processed, renovated or let on hire by the **Insured** and no longer in the direct possession or control of the **Insured**.

Property damage

Property damage means physical injury to tangible property including the resulting loss of use of that property. All such loss of use shall be deemed to occur at the same time of the physical injury that caused it.

Research subject

Research subject means any person participating in a **trial** or the pre **trial** assessment including their dependants, heirs and legal representatives and including any child injured in utero through the participation of its mother in a **trial.**

Subsidiary

Subsidiary means any incorporated or registered Organization over which the first named insured shown in the Schedule controls, either directly or indirectly, more than 50 percent of the interests entitled to vote generally in the election of the governing body of such Organization.

Trial	**Trial** meaning any human clinical **trial** or Healthy Volunteer Study conducted to test a **drug**, **medical device** or a material within or upon human beings to establish the effectiveness or safety of such material.
Trial period	**Trial period** meaning the start date and the end date of the **trial** shown in the Trial Master Schedule

Conditions

Assignment	Assignment of interest under this insurance shall not bind the Company without its written consent.
Arbitration	Any dispute concerning the interpretation of the terms, exclusions or conditions contained herein is understood and agreed to by both the **Insured** and the Company to be subject to Indian law. If any difference arises as to the amount to be paid under this Policy (liability being otherwise admitted) or the interpretation of a clause under the Policy (including the Schedule and Endorsements), such difference shall be referred to arbitration at Mumbai, India, in accordance with the Indian Arbitration and Conciliation Act 1996, as amended, and the making of an award shall be a condition precedent to any liability for the Company to make any payment under this Policy.
Compliance	The **Insured** shall ensure that all Trials comply with applicable agreements, laws, regulations, procedures of the relevant person, authority department public or private body in the country in which the **trial** occurred. Cover will not apply if the **Insured** knowingly or negligently violates any such applicable agreements, laws, regulations, procedures.
Contribution	If at the time of any loss, destruction or **occurrence** giving rise to liability under this policy, there be any other policy of insurance covering such loss, destruction or **occurrence** or any part thereof, the Company shall not be liable for more than its rateable proportion thereof, and shall not in any event be liable in respect of subject matter of insurance of any description specifically **Insured** by any such other policy or be brought into contribution in any loss applying to such property.
Declaration	When the subject matter of insurance under this policy is insured on a declaration basis, the **Insured** shall report total number of **trial**s conducted during the Policy Period together with its details like drug, medical devise or material, number of participants, duration of the trial etc. to the Company within 30 days of the expiration of the policy period or as otherwise stated in this policy. Any provisional premium shall be adjusted by applying the agreed rate to the average of the total **trial**s on cover..
Dispute Procedure	Any dispute concerning the interpretation of the terms, conditions, limitations and/or exclusions contained in this Policy is understood and agreed by both the **Insured** and the Company to be subject to Indian law. Each party agrees to submit to the jurisdiction of such court within india and to comply with all

requirements necessary to give such Court jurisdiction.

Due Diligence

The **Insured** shall use due diligence and carry out all things reasonably practicable to avoid or diminish any loss or any circumstance likely to give rise to a **claim** insured under this policy.

Due Observance

The due observance of the terms, provisions and amendments of this policy by the **Insured** in so far as they relate to anything to be done or compiled with by the **Insured** and the truth of the statements and answers and information supplied on or in connection with the proposal shall be a condition precedent to any liability of the Company to make any payment under this policy.

Governing Law

The Policy will be construed and interpreted in accordance with Indian law and the parties submit to the non exclusive jurisdiction of the Indian Courts.

Grievances

Any person who has a grievance against us, may himself or through his legal heirs make a complaint in writing to the Insurance Ombudsman in accordance with the procedure contained in The Indian Redressal of Public Grievance Rules, 1998 (Ombudsman Rules). Proviso to Rule 16(2) of the Ombudsman Rules, however, limits compensation that may be awarded by the Ombudsman, to the lower of compensation necessary to cover the loss or damage suffered by you as a direct consequence of the insured peril or Rs. 20 lakhs (Indian Rupees Twenty Lakhs Only) inclusive of ex-gratia and other expenses. A copy of the said Rules shall be made available by us upon prior written request by you.

Inspections And Surveys

We have the right but are not obligated to:

- make inspections and surveys at any time;
- give you reports on the conditions we find; and
- recommend changes

Any inspections, surveys, reports or recommendations relate only to insurability and the premiums to be charged. We do not make safety inspections. We do not undertake to perform the duty of any person or organisation to provide for the health or safety of workers or the public. We also do not warrant that conditions

- are safe or healthful; or
- comply with laws, regulations, codes or standards.

This condition applies not only to us, but also to any rating, advisory, rate service or similar organisations which make insurance inspections, surveys, reports or recommendations that are used by us to determine insurability and the premiums to be charged

Material Alteration

The **Insured** shall advise the Company immediately in writing of any alteration which materially affects the risk **Insured**.

Misrepresentation and Fraud

Coverage shall be void if the **Insured** knowingly concealed or misinterpreted any material fact or circumstance concerning this insurance or the subject thereof, or in the case of any fraud or false swearing by the **Insured** relating to this insurance or the subject therefore, whether before or after a loss. Further, if the **Insured** shall make any **claim** knowing the same to be false or fraudulent as regards amount or otherwise, this policy shall become void in respect of the specific **claim** and the Company shall have the right to terminate this policy with all future **claims** hereunder by the **Insured** being forfeited.

New Trials

For any new trial not described in the Trial Master Schedule this insurance applies only if:

- **Insured** give us written notice describing the trial for which coverage is requested;
- Company agree to issue an endorsement to provide coverage in connection with the trial, in accordance with the terms, conditions and additional premiums determined by us; and
- **Insured** accept such terms and conditions.

Notice of termination in the event of loss

In the event of loss, the **Insured** and the Company are both entitled to give notice terminating the insurance to take effect 30 days after the notice of termination, whereupon the unused portion of the premium shall be repaid. However, such part of the premium as corresponds with the Company's costs for losses during the insurance period shall be considered used.

Reasonable Precaution

The **Insured** shall take all reasonable precautions to prevent injury, loss or damage.

Renewal

Renewal of policy will be done after agreement with the **Insured.**

Subrogation

The Company shall have rights of subrogation to all the **Insured**'s rights of recovery against any person or organization before or after any payment under this insurance. The **Insured** shall execute and deliver instruments and papers and do whatever else is necessary to secure such rights. The **Insured** shall do nothing after loss to prejudice such rights. For the purpose of this paragraph, the word "**Insured**" includes any **Insured** under any applicable liability schedule.

Extension

Subject otherwise to the terms, exclusions, limits, conditions and endorsements of this Policy, coverage is extended as follows:

Compassionate Use

Compassionate use of the **drug** tested after the period of the study can be covered only if :

- **Insured** give us written notice describing the **drug** or material for which coverage is requested;
- Company agree to issue an endorsement to provide coverage in connection with the **drug** or material, in accordance with the terms, conditions and additional premiums determined by us; and

- **Insured** accept such terms and conditions.

Cross Liability Clause

The Company will indemnify each person comprising the **Insured** in the same manner and to the same extent as if a separate policy had been issued to each provided that the total liability of the Company in respect of all such parties shall not exceed the Limit of Liability shown in the Schedule.

STATUTORY NOTICE: "INSURANCE IS THE SUBJECT MATTER OF SOLICITATION."