



ROYAL SUNDARAM INSURANCE
Sundaram Finance Group

ROYAL SUNDARAM GENERAL INSURANCE CO. LIMITED

Regd. Office: 21, Patullos Road, Chennai 600 002.

Corporate Office: "Vishranthi Melaram Towers", 2/319, Rajiv Gandhi Salai,
Karapakkam, Chennai 600 097.

Ph: 91-44-7117 7117, 1860 425 0000.

Email: customer.services@royalsundaram.in

Website: www.royalsundaram.in

IRDA Regn. No. 102 | CIN-U67200TN2000PLC045611

CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

NO FAULT COMPENSATION INSURANCE FOR CLINICAL TRIALS AND/OR HUMAN VOLUNTEERS STUDIES

(This is a "claims made" Policy)

We, Royal Sundaram Alliance Insurance Company Limited (hereinafter called "the Company") in consideration of the payment of premium by the Insured and subject to all terms Definitions Limits of Indemnity Exceptions Conditions and any Memoranda endorsed hereon will indemnify the Insured as provided herein

Date: _____

Signe: _____

For and on behalf of

Royal Sundaram Alliance Insurance Company
Limited

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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

Policy No	:	
The Insured	:	
Test Centre: Business	:	The undertaking of a Trial by or on behalf of the Insured for a Phase Study of the drug " "
Study Title	:	(Protocol No.:)
Period of Insurance	:	From to
Trial Period of the Program	:	Months
Limits of Indemnity	:	The liability of the Company shall not exceed INR per patient and INR in the aggregate for the entire protocol during Period of Insurance
Retroactive Date	:	from inception of policy
Minimum & Deposit Premium	:	INR
Rate	:	INR Per Patient
No. of tested persons	:	Not More than
Policy Territory	:	Indian Only
Jurisdiction	:	Indian Only
Deduction	:	INR Each and Every Loss
Condition	:	1. Compensation guidelines to be agreed by the Insured and the Tested subjects 2. Approval from government authority and ethics committee. 3. War & Terrorism Exclusion
Broker	:	

*****END OF THE SCHEDULE*****



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

(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 Policy

but only 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 mental 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 relation 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

For the purpose of this Policy the date of such demand shall represent the date the Claim is first made against the Insured

(8) Research Subject shall mean any person participating in a Trial including their dependents their executor's administrators and legal representatives



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

(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 any 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 300a 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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

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 results 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 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 Indemnity set forth in the Schedule or extend the Period of Insurance

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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

- (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 (LAV) or the mutant's 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 of 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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

- f. Clindamycin
- g. Lincomycin
- h. Debendox
- i. Halogenated 8 Hydroxy Quinolines
- j. Phen/Fen

CONDITONS 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 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 application in the country in which the Claim is made



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

- (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



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

(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 withheld 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 withheld 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 extent 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 extent of the actual changes in the protocol.



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

(14) No claim shall be payable unless the insured c[aims 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

(i5) 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 •ive rise to a Claim



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

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

(7j) 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 defense 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 defense 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 be entitled to a refund a ratable 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.



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

Short Period Rate

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 up to 90 days

50% of Annual Premium

Exceeding 90 days and up to 180 days Above 180 days

75% of Annual Premium

Above 180 Days

Full Annual Premium - No refund is allowed

ARBITRATION

The parties to the contract may mutually agree and enter into a separate Arbitration Agreement to settle any and all disputes in relation to this policy. Arbitration shall be conducted under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996.

Clause J. Grievances

If You have a grievance about any matter relating to the Policy, or Our decision on any matter, or the claim, You can address Your grievance as follows:

1. Our Grievance Redressal Officer

If You have a grievance about any matter relating to the Policy, or Our decision on any matter, or the claim, You can address Your grievance as follows.

1. In case of any grievance You may contact the company through

Website: <https://www.royalsundaram.in/customer-service>

Contact Numbers: 1860 258 0000, 1860 425 0000

E-mail: manager.care@royalsundaram.in



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

Sr. Citizen can email us at: seniorcitizengrievances@royalsundaram.in

Fax: 044-7117 7140

Courier: Grievance Redressal Unit

Royal Sundaram General Insurance Co. Limited

Vishranthi Melaram Towers,

No.2/319, Rajiv Gandhi Salai (OMR) Karapakkam,

Chennai – 600097.

You may also approach the grievance cell at any of the company's branches with the details of grievance.

If You are not satisfied with the redressal of grievance through one of the above methods, You may contact the grievance officer

Mr. T M Shyamsunder

Grievance Redressal Officer,

Royal Sundaram General Insurance Co. Limited,

Vishranthi Melaram Towers, No.2/319, Rajiv Gandhi Salai (OMR),

Karapakkam, Chennai – 600097.

For updated details of grievance officer, kindly refer the link <http://www.royalsundaram.in>.

If You are not satisfied with the redressal of grievance through above methods, the You may also

approach the office of Insurance Ombudsman of the respective area/region for redressal of grievance as per Insurance Ombudsman Rules 2017. Grievance may also be lodged at IRDAI Integrated Grievance Management system <https://bimabharosa.irdai.gov.in>.

2. Consumer Affairs Department of IRDAI

a. In case if it is not resolved within 15 days or if You are unhappy with the resolution, You can approach the Grievance Redressal Cell of the Consumer Affairs Department of IRDAI by calling Toll Free



CLINICAL TRIALS LIABILITY POLICY

UIN: IRDAN102CP0001V01201112

Policy Wordings

Number 155255 (or) 1800 4254 732 or sending an e-mail to complaints@irdai.gov.in. You can also make use of IRDAI's online portal – Bima Bharosa Portal by registering Your complaint at <https://bimabharosa.irdai.gov.in/>

b. You can send a letter to IRDAI with Your complaint on a Complaint Registration Form available by clicking here. You must fill and send the Complaint Registration Form along with any documents by post or courier to General Manager, Insurance Regulatory and Development Authority of India (IRDAI), Consumer Affairs Department - Grievance Redressal Cell, Sy.No.115/1, Financial District, Nanakramguda, Gachibowli, Hyderabad- 500032.

c. You can visit the portal <https://bimabharosa.irdai.gov.in/> for more details.

3. Insurance Ombudsman

You can approach the Insurance Ombudsman depending on the nature of grievance and financial implication, if any. Information about Insurance Ombudsmen, their jurisdiction and powers is available on the website of the Insurance Regulatory and Development Authority of India (IRDAI) at www.irdai.gov.in or of the General Insurance Council at <https://www.cioins.co.in/ombudsman> or on company website www.royalsundaram.in.