

Introduction:

Clinical Trial Liability Insurance protects the organizations that conduct human research from financial loss due to potential harm or injury to volunteer participants. Clinical trials refer to scientific tests and treatments experimented on people to understand the efficacy of a medicine or medication. A clinical trial insurance covers physical injury, loss of data or property which occurs during the trial.

Who can avail of "Clinical Trial Liability"?

Clinical Trial Liability Insurance is primarily availed by the sponsor, the clinical research organization (CRO), the investigating institution(s), and individual investigators.

What is the coverage under the policy?

We 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.

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.

Research Subjects shall mean any person participating in a Trial including their dependents their executor's administrators and legal representatives.

What are the exclusions under the policy?

The Company shall not be liable for

- (1) any consequence whether direct or indirect of war invasion act of foreign enemy hostilities (whether war be declared or not) civil war rebellion revolution insurrection military or usurped power
- (2) any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from
 - (a) ionizing radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel
 - (b) the radioactive toxic explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof



- (3) any Claim arising from Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (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. Diethylstilboestrol
 - b. Stilbestrol/D.E.S.
 - c. Primodos
 - d. Amenorone-Forte
 - e. Swine-Flu Vaccine.
 - f. Clindamycin
 - g. Lincomycin
 - h. Debendox
 - i. Halogenated 8 Hydroxy Quinolines
 - j. Phen/Fen

Cancellation

1. 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.
2. 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.

Grievance Redressal Procedure:

1. In case of any grievance the insured person 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
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.

The insured may also approach the grievance cell at any of the company's branches with the details of the grievance. If the insured is not satisfied with the redressal of the grievance through one of the above methods, the insured 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 the grievance officer, kindly refer the link <http://www.royalsundaram.in>.

If Insured is not satisfied with the redressal of the grievance through the above methods, the insured may also approach the office of Insurance Ombudsman of the respective area/region for redressal of the 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 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 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

If the **Insured** is not satisfied with the redressal of grievance through the above methods, the **Insured** may also approach the office of the Insurance Ombudsman of the respective area/region for redressal of grievance as per the Insurance Ombudsman Rules 2017. You can approach the Council for Insurance Ombudsman depending on the nature of the grievance and financial implications, 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. For the updated list of the offices of the Insurance Ombudsman, we request you to visit the website of the Council for Insurance Ombudsman at <https://www.cioins.co.in/ombudsman> or on our company website at www.royalsundaram.in. You can also lodge an online complaint with the Council for Insurance Ombudsman through the website of the Council for Insurance Ombudsmen (CIO) at www.cioins.co.in



Section 41 in the Insurance Act, 1938

41. Prohibition of rebates

(1) No person shall allow or offer to allow, either directly or indirectly, as an inducement to any person to take out or renew or continue an insurance in respect of any kind of risk relating to lives or property in India, any rebate of the whole or part of the commission payable or any rebate of the premium shown on the policy, nor shall any person taking out or renewing or continuing a policy accept any rebate, except such rebate as may be allowed in accordance with the published prospectuses or tables of the insurer: Provided that acceptance by an insurance agent of commission in connection with a policy of life insurance taken out by himself on his own life shall not be deemed to be acceptance of a rebate of premium within the meaning of this sub-section if at the time of such acceptance the insurance agent satisfies the prescribed conditions establishing that he is a bona fide insurance agent employed by the insurer.

(2) Any person making default in complying with the provisions of this section shall be liable for a penalty which may extend to ten lakh rupees.

Note: In case of any conflict, the terms and conditions mentioned in the policy document shall prevail.