Clinical Trials Liability Insurance
Prospectus

The Underwriters 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 Trial(s) of the Insured as stated in the Schedule.

Scope of Cover

The Clinical Trials Insurance policy covers legal liability arising out of:

- Lack of care, negligence and its resulting bodily Injury or death of Research Subject (person participating in the Trial)
- All reasonable Legal Costs & expenses including Defence cost as per the compensation guidelines

Some of the other highlights of the policy are:

- Cover for Research subject in case of death/injury. Research subject means dependants, heirs, executors, administrators and legal representatives.
- Provision to pay compensation as per the compensation guidelines in the policy
- Manslaughter Defence Costs (Ethics Committee)
- Cover can be extended to cover full medical expenses

Major Exclusions

- Studies/trials undertaken without written prior consent of the Research Subject
- Trials Outside India (unless specifically covered)
- Violation of Law/Regulations
- Any occurrence w.r.t which the insured was aware before policy start date
- Any Occurrence after policy period
- Payments which aren't allowed under Sanctions imposed (e.g. Sanctions by UN, EU, USA)

Limit of Liability

- The limit of Indemnity under policy is estimated on the basis of aggregate limit. An aggregate limit is the most an insurer will pay during the policy period.

- There is a provision of increasing the aggregate limit on payment of additional premium, the aggregate limit can be increased by way of an endorsement. This can be out of increase in the business of the insured or new contractual requirement of the Insured.

The policy can be annual as well as multi year.

Benefits of buying this policy

- This policy will help in protecting business from claims arising out of injuries caused to subjects during trial
- It helps to fulfil the regulatory/compliance or contractual needs

Claims

The Insured must submit claims notifications in writing to:
ICICI Lombard General Insurance Company Limited
ICICI Lombard House, 414,
Veer Savarkar Marg, Prabhadevi Mumbai 400 025
Such notice shall be effective on the date of receipt by the Company at such address.

Cancellation

The Insured can cancel the policy at any time during the term, by informing the company. The Company can cancel the policy only on the grounds of established fraud, by giving minimum notice of 7 days to the policyholder.
The Company shall –
i) refund proportion premium for unexpired policy period, if the term of the policy is upto one year and there is no claim(s) made during the policy period.
ii) refund premium for the unexpired policy period, in respect of policy with the term more than one year and the risk coverage for such policy years has not commenced.

Grievance Redressal

For resolution of any query or grievance, Insured may contact the respective branch office of the Company or may call toll free no.1800-2666 or may approach us at the sub section “Grievance Redressal” on our website www.icicilombard.com (Customer Support section). However, if the resolution provided by us is not satisfactory you may approach Insurance Regulatory and Development Authority of India (IRDAI) through the Bima Bharosa Portal - https://bimabharosa.irdai.gov.in/ or IRDAI Grievance Call Centre (IGCC) at their toll free no. 1800 4254 732 / 155255.
You may also approach Insurance Ombudsman, subject to vested jurisdiction, for the redressal of grievance. Details of Insurance Ombudsman offices are available at IRDAI website: www.irdai.gov.in, or on the Company’s website at www.icicilombard.com

STATUTORY WARNING

PROHIBITION OF REBATES

(Under Section 41 of Insurance Act 1938)

(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 any class of insurance business taken out by himself in relation to risks associated with his own life, health or property 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.