

**CLINICAL TRIALS AND/OR HUMAN VOLUNTEERS STUDIES INSURANCE
PRODUCT INFORMATION STATEMENT**

The Product Information Statement is intended to facilitate an easier understanding of the policy terms, conditions and exclusions. It only gives a summary of the significant benefits and risks associated with this product. The policy attached with this statement represents the legal contract between yourself and Raheja QBE General Insurance Co. Ltd and should be seen for complete details.

If you need any clarification on coverage please call your nearest Raheja QBE office or your insurance adviser.

Why Clinical Trials Insurance Policy?

Clinical Trials are vital and important for finding new, better & more effective Medicine. Whenever any new medicine/therapy is to be launched, it must first be tested in lab on animal or human cell. If the results are encouraging than it is tested on human being. There is commercial advantage to the firm that produce the first approved drug for a disease. That being the position there is dramatic increase of clinical Trials. India has now become a favourable destination for clinical Trials because of availability of expertise , infrastructure, availability of patient /research subject, low cost. In any case, in today's litigant society, parties are sued regardless of who or what caused injury or death.

This being the ground reality, insurance must form part of any risk management philosophy of the company interested in clinical time. As a part of any clinical trial, therefore, need proper monitoring and proper insurance cover. Even then in spite of all precautions being there, liability will arise because of the human element and other factor and hence need insurance.

Scope of Cover

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

- Lack of care, negligence, 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:

- A broad definition of Insured under the policy
- Cover for Research subject in case of death/injury. Research subject means dependants, heirs, executors, administrators and legal representatives.



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- 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

(For a detailed explanation of the above covers please refer Raheja QBE's Clinical Trials Insurance policy document)

Exclusions

The following are excluded under the policy and are not covered:

- War and invasion
- Radioactivity and Nuclear
- Prior or Subsequent Discovery of Loss
- Failure of Product/Drug
- Failure to cure or alleviate
- Terrorism
- Asbestos
- Mould
- Financial Loss not consequent upon bodily injury
- costs incurred on repair or replacement
- Product Recall

Dispute Resolution

Raheja QBE will take all steps to settle your claim in accordance with policy terms and conditions. However, since the policy does not cover all eventualities, there may be disagreement on settlement of the claim.

For resolution of such disputes Raheja QBE has developed an elaborate Grievance Redressal mechanism.

At your request, the claim will be considered afresh by the Grievance Committee of Raheja QBE. If you are not satisfied with the decision of the Grievance Committee you may refer your case to the Insurance Ombudsman. Please call Raheja QBE offices to ascertain if you are eligible for such a reference.

Important Notice:

This document is for your information and the description herein is a summary only. It does not attempt to provide full details of every aspect of cover, nor all exclusions or limitations which apply. For full details or clarifications, please read our policy wordings which are available on request or contact your insurance advisor.

Insurance is the subject matter of solicitation.