

PROPOSAL FORM - CLINICAL TRIALS LIABILITY POLICY

Outline of planned feasibility and clinical evaluation protocols

PROTOCOL SYNOPSIS

NEED FOR THE STUDY

STUDY TITLE :

INVESTIGATIONAL DRUG:

DOSE/DOSAGE FORM/ROA:

STUDY POPULATION:

SAMPLE SIZE:

CLINICAL PHASE:

OBJECTIVE

EFFICACY ENDPOINTS :

PRIMARY:

SAFETY MEASUREMENTS

RATIONALE

DATA ANALYSIS

Details of each test as well as the purpose.
Examinations planned during the trial (eg. blood parameters, x-ray...)

PROTOCOL DEVELOPMENT RESOURCES:

COVERAGE REQUIRED:

Limit of Liability Aggregate AOY:

Any one Accident Limit AOA:

Limit Per volunteer/Subject:

Territorial Scope of cover/Jurisdiction:

Additional details:

- 1) Are all trials/studies in full accordance with:
 - a) Department of health requirements with protocols approved by an independent ethics committee?
.....
 - b) Royal College of Physicians recommendations?
.....
 - c) Applicable Government Department or Medical Body or Pharmaceutical Industry Body Guidelines?
.....
 - d) ICH Guidelines on Good Clinical Practice
.....
- 2) Are all trials/studies conducted in India? If not show summaries of trials in each country
.....
- 3) If applicable, are all rights of recourse retained against product manufacturers?
.....
- 4) Are all volunteers tested for HIV and Hepatitis prior to entering trial?
.....
- 5) Details of incidents during the last 5 years resulting in death injury, disease or illness to patients or volunteers or any circumstances, which might give, rise to claim for compensation.
.....
- 6) Summary of trial/studies performed in the last twelve months: Date commenced, Title/description, country, phase, Number of volunteers.
.....

PRE-CLINICAL SUPPORTING DATA:

QUALITY ASSURANCE:

ANALYSIS OF THE STUDY:

Any additional information relevant to the Policy
Note: Please use additional sheets if space is not sufficient to complete details

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DECLARATION

I/We authorise the Company and all other group companies of ICICI Bank Group and their agents to exchange, share or part with all the information relating to my personal and financial details and information to other ICICI Bank Group companies/ Banks/ Financial Institutions/ Credit Bureau/ Agencies/ Statutory Bodies as may be required and I/We will not hold the Company and all other group companies of ICICI Bank Group and their agents liable for use of this information.

I/We agree that the Policy shall become voidable at the option of the Company, in the event of any untrue or incorrect statement, misrepresentation, non-description or non-disclosure in any material particular in the proposal form/personal statement, declaration and connected documents, or any material information has been withheld by me/us or anyone acting on my/our behalf to obtain any benefit under this Policy.

I/We, the undersigned hereby declare and warrant that the above statements are true, accurate and complete. I/We desire to effect an insurance as described herein with the Company and I/We agree that this proposal and declarations hereto shall be the basis of contract between me/us and the Company and I/We agree to accept a Policy subject to the conditions prescribed by the Company.

I/We agree that the issuance of Policy/Cover Note shall be subject to realisation of premium cheque.

I/We hereby agree and confirm that if the amount collected is less than the premium quoted or revised as per changes in sum proposed for insurance or scope of cover desired by me/us, the proposal shall be considered for acceptance for a reduced sum appropriate to the premium collected and the Policy shall be finalised accordingly.

Place: _____

Proposer's Signature: _____

Company stamp

Date:

D	D	M	M	Y	Y	Y	Y
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Name: _____ Designation _____

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.
2. Any person making default in complying with the provisions of this section shall be punishable with fine, which may extend to five hundred rupees.