Clinical Trials/ BE Study Liability Insurance

PROPOSAL FORM

Business Sector: Urban /Rural /Social
Name of Relationship Manager:
Proposal Form No: Group I.D.No: Client I.D.No:

GUIDELINES FOR COMPLETION OF THE FORM

1. Please answer all questions fully and correctly. Where any question does not apply, please mention clearly that the same is not applicable.
2. Insurance is a contract of Utmost Good Faith requiring the Insured not only to disclose all material facts but also not to suppress any material facts in response to the questions in the proposal form. If you think any fact is material, please disclose it.
3. The Policy shall become voidable at the option of the Insurer, in the event of any untrue or incorrect statement, misrepresentation, non-description or on non-disclosure in any material particular in the proposal form/personal statement, declaration and connected documents, or any material information having been withheld by the proposer or any one acting on his behalf.
4. Kindly contact the Company's Offices or Agents for any doubts or clarifications on the proposal form.

NOTE
The liability of the Company does not commence until this proposal has been accepted by the Company and premium paid.
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SCOPE OF COVER
This insurance Policy indemnifies the Insured against legal liability of the Insured in connection with the clinical trial/BE study covered under this Policy. The Policy also covers legal costs and expenses incurred by the Insured, with prior consent of the Company and within the sum insured, in the investigation, defence or settlement of such legal liability.

SIGNIFICANT EXCLUSIONS
kindly refer to the Policy wordings

EXTENSIONS
In addition, certain optional extensions are available, the details of which are provided in the relevant section of this proposal form.

NOTE: The foregoing is only an indication of the cover offered. For details, please refer to the Policy.

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DETAILS : Put a (✔) mark wherever applicable

COMPANY NAME AND ADDRESS:
PRODUCT INFORMATION:
PRODUCT DESCRIPTION:
Composition:
Manufacturing Process:
Summary of hazards identified or anticipated, their causes and associated risks, and proposed mitigating action:
Any registration for this product in another country already:
Past/ Other Trial data for this product:
DESCRIPTION OF INTENDED USE:
DOSE/DOSAGE FORM/ROA: **STUDY POPULATION:**
OBSERVATION PERIOD:

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EFFICACY END POINT :

PROBANDS

How many probands will participate?

Inclusion and exclusion criteria of the probands.

INCLUSION CRITERIA:

EXCLUSION CRITERIA:

Profile of probands: age, sex, race, health status, co-medication

BACKGROUND INFORMATION

Brief summary of all applicable clinical investigations or research conducted by the sponsor

SUMMARY OF PLANNED MAJOR PRE-CLINICAL AND CLINICAL ACTIVITIES

Time-Schedule for the trial

Outline of planned feasibility and clinical evaluation protocols

PROTOCOL SYNOPSIS

PROTOCOL NUMBER:

NEED FOR THE STUDY

STUDY TITLE

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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:

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Limit of Liability Aggregate AOY:	**INR**
Any one Accident Limit AOA:	**INR**
Limit Per volunteer/Subject:	**INR**
Territorial Scope of cover:	
Jurisdiction:	

Are you aware of any such event/situation/accident that can lead to Clinical Trials/BE Study Liability Claim? NO / YES

(incase of Yes, please provide full details)

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:

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ANALYSIS OF THE STUDY:

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

Documents to be attached with proposal form:

1. **Copy of Study protocol**
2. **Specimen copy of Informed Consent form**
3. **Specimen copy of SADR reporting form (serious adverse drug reaction)**
4. **Specimen copy of Sponsorer's contract with other parties involved in the trials (e.g. CRO etc.)**
5. **Specimen of case record form**

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_____

Initials of Proposer

Date: (DD-MM-YYYY)

Name: _____Designation _____

Company stamp

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.

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