PROPOSAL FORM - CLINICAL TRIALS LIABILITY INSURANCE

GUIDELINES FOR COMPLETION OF PROPOSAL

1. Please answer all questions on this Proposal completely, accurately and correctly. For all questions that do not apply, please mention clearly that the question is Not Applicable (Note: all questions answered "NA" will be considered to be answered as Not Applicable).
2. This Proposal must be SIGNED, STAMPED and DATED by an authorised signatory of the proposed policyholder.
3. Insurance is a contract of Utmost Good Faith which requires the proposed policyholder to disclose all material facts in relation to this Proposal in respect of the proposed policyholder and each proposed Insured and to also not suppress any material facts in relation to this Proposal while responding to the questions in the Proposal. If You believe that any fact/ information / documentation is material to this Proposal then You must disclose it to the Insurer. The Policy shall become voidable at the option of the Insurer, in the event of any untrue or incorrect or incomplete statement, misrepresentation, non-description or on non-disclosure in any material particular in the Proposal/personal statement, declaration and connected documents, or any material information having been withheld by the proposed policyholder or any one acting on its behalf to obtain any benefit under this Policy.
4. If You require additional space to answer any question on this Proposal, please attach additional sheets of paper and indicate on the additional sheet the question number to which the information being provided pertains.
5. Kindly contact the Insurer's Offices or Agents or Your broker for any queries or clarifications that You may have on the Proposal or the questions contained therein.
6. The proposed policyholder will be referred to in this Proposal as "proposed policyholder", "You" or "Your".

Note: The liability of the Insurer in relation to the subject matter of this Proposal shall not commence until this Proposal has been accepted by the Insurer through issuance of the Policy Document/Cover Note and subject to the receipt of premium by the Insurer.

DETAILS: Put a (✓) mark wherever applicable

Company Name and Address:

Pin Code Contact Details

Email ID

Product Information:

Product Description:

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:

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

Do you wish to avail policy documents in physical form ☐ Yes ☐ No

Nominee Name

Relationship with the Insured

Mobile No. Email ID

Present & Permanent Address

Authorized person for Minor Nominee

Bank Details

Details of Multiple/Other insurance covering same risks with any other Insurance Company: _____

_____

_____

Type of Proposer ☐ Individual ☐ MSME/SME ☐ Partnership firm ☐ Company ☐ Govt. ☐ Others _____

Are you or any of the proposed applicants/beneficial owner a PEP* or Family member/ Close relatives/Associates of PEPs*?

☐ Yes ☐ No

If yes, please give details (Nature of relationship and position held by PEP):_____

**Politically Exposed Persons (PEPs) are individuals who have been entrusted with prominent public functions by a foreign country, including the heads of States or Government, senior politicians, senior government or judicial or military officers, senior executives of state-owned corporations and important political party officials.*

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 0 0 : 0 0 hour

Outline of planned feasibility and clinical evaluation protocols

Protocol Synopsis

Protocol Number:

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: INR

Any one Accident Limit AOA: INR

Limit Per volunteer/Subject: INR

Policy Period: From: D D / M M / Y Y Y Y To : D D / M M / Y Y Y Y

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

Analysis Of The Study

Mandatory

As per the IRDA Circular No.: IRDA/F&A/CIR/GLD/056/02/2014, policyholder's bank account details are mandatory to process the claim through EFT, please provide the below details (all fields are compulsory) and provide a cancelled cheque of the policyholder's (should be of the bank account number mentioned below)

DETAILS OF BANK ACCOUNT

Proposed policyholder's name (as per bank record):

Proposed policyholder's account no.:

Name of Bank Branch

Address of the bank:

MICR Code (9 digit) IFSC Code (11 digit)

PAN card no. of the proposed policyholder:

BANK DETAILS

Refund of Premium (Policyholder/Proposer)

Account Holder Name

Bank Name

Account No. IFSC Code

Documents to be attached with proposal form:

Copy of Study protocol

Specimen copy of Informed Consent form

Specimen copy of SADR reporting form (serious adverse drug reaction)

Specimen copy of Sponsorer's contract with other parties involved in the trials (e.g. CRO etc.)

Specimen of case record form

DECLARATION WHEN THE PROPOSAL FORM IS FILLED BY A PERSON OTHER THAN THE PROPOSER/ THE PROPOSER SIGNS IN A VERNACULAR LANGUAGE/ PROPOSER IS ILLITERATE

- I hereby declare that I have read out and explained the content of this proposal form and all other connected documents incidental to availing the insurance policy from ICICI Lombard GIC ltd. to the proposer and that he/she confirmed that he/she has understood the same and he/she agrees to abide by all terms and conditions of the same.
- I hereby declare that I have fully explained to the proposer the answers to the questions that form the basis of the contract of insurance have also explained the contents in this form to the proposer in _____ language, that I have truly correctly recorded the answers given by the proposer and that the proposer has fixed his/her thumb impression on the proposal form in my presence, after fully understanding the contents thereof. Further, this declaration does not confirm issuance of policy or assumption of risk thereof.
- I hereby state that the contents of the form and documents have been fully explained to me and that I have fully understood the significance of the proposed contract.

Name of the Proposer

Name of the Witness

Signature of Proposer	Signature of Witness

Place: _____ Date D D M M Y Y Y Y

Relationship with Proposer

Address of Witness

Declaration by Proposed Policyholder

I/We agree that the Policy shall become voidable at the option of the Insurer, in the event of any untrue or incorrect statement, misrepresentation, non-description or non-disclosure in any material particular in the Proposal/personal statement, declaration and connected documents, or if 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 Insurer and I/We agree that this Proposal and declarations hereto shall be the basis of contract between me/us and the Insurer and shall be incorporated into the Policy (if) issued on the basis of this Proposal. I/We agree to accept a Policy subject to the conditions prescribed by the Insurer.

I/We agree that the issuance of Policy/Cover Note and the cover under the Policy shall commence subject to realisation of the premium cheque by the Insurer.

I/We hereby agree and confirm that if the amount collected is less than the premium quoted or revised as per changes in Limit of Liability 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.

I/We hereby give my/our consent to the Company to verify and obtain my/our identity/address proof as well as the identity / address proof of the insured through Central KYC Registry or UIDAI or through any other modes for the purpose of undertaking KYC.

I/We hereby declare and confirm that the premium has been paid out of legally acquired sources of income and the subsequent premiums if any, will continue to be paid out of legally declared and assessed source of income.

I/We understand that the Company has right to call for documents to establish source of funds

I/We hereby declare that the details furnished above are true and correct to the best of my/our knowledge and belief and I/we undertake to inform you of any changes therein, immediately, not later than 30 days.

In case any of the above information is found to be false or untrue or misleading or misrepresenting, I am/we are aware that I/we may be held liable for it.

Place :

Proposers Signature_____

Date : D D / M M / Y Y Y Y

Name:_____ Designation_____

INTERMEDIARY DECLARATION AND DETAILS/PRINCIPAL OFFICER DETAILS

I, _____<full name> in my capacity as an Insurance Advisor/ Specified Person of the Corporate Agent/ Insurance Sales Persons of Insurance Marketing Firm / Broker Qualified Person/ Point of Sales Person/ Designated Person/ Authorised Verifier or any other authorised salesperson/ Rural Authorized Person (RAP) and Village Level Entrepreneur – Ins (VLE-Ins) of Common Public Service Centre do hereby declare that I have explained all the contents of this Proposal Form, including the nature of the questions contained in this Proposal Form to the Proposer including statement(s), information and response(s) submitted by him/her in this Proposal Form to questions contained herein or any details sought herein will form the basis of the Contract of Insurance between the Company and the Proposer, if this Proposal is accepted by the Company for issuance of the Policy. I have further explained that if any untrue statement(s)/ information/response(s) is/are contained in this Proposal Form/including addendum(s), affidavits, statements, submissions, furnished/to be furnished, the Company shall have the right to cancel the policy at its discretion. Further, this declaration does not confirm issuance of policy or assumption of risk thereof.

_____ (to be filled in, only in case there is some disclosure to be made).

I hereby confirm to the best of my knowledge and belief that there is no inconsistency or adverse habits that may affect the underwriting of this proposal except as mentioned below:

Intermediary Name / Principal Officer Name: _____ Code/Functional Identity: _____

Contact No. of the branch: _____ Email ID of the branch: _____ Branch/Office: _____

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.