

Customer Information Sheet
SER Clinical Trial Insurance

This document provides only key information about your policy. Please refer to the policy document for detailed terms and conditions.

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
1	Product Name	SER Clinical Trial Insurance	NA
2	Unique Identification Number (UIN) allotted by IRDAI	IRDAN125CP0047V01200910	NA
3	Structure	State basis of Sum / Limit Insured Section I- Benefit Basis Section II & III- Indemnity Basis	NA
4	Interests Insured	Company/Individual undergoing Clinical trial	Who is an Insured
5	Sum Insured	<<as per policy schedule>>	Policy schedule
6	Policy Coverage	<p>The Covers offered under the respective sections are as follows:</p> <p>Section 1 - Settlement with Mediation - Indemnifies the Insured, for all sums which the Insured shall pay to a research subject as a result of a settlement agreement reached between the research subject and the Insured, in the event of a claim by the research subject against the insured arising out of the research subject's participation in a trial commencing within the Policy Period.</p> <p>Section 2- Legal Liability – Indemnifies the Insured, for all sums including legal costs which the Insured shall be legally liable to pay as damages and compensation awarded by a court for property damage as well as bodily injury, personal injury and advertising injury caused to a research subject by the research subject's participation in a trial commencing within the Policy Period.</p> <p>Section 3- Medical payments Coverage – The Company will pay for medical payments in respect of each research subject who sustains bodily injury arising out of their participation in a trial when such injury was incurred during the Trial Period and reported to the Company within one year from the date of sustaining the bodily injury. This section excludes medical payments for bodily injury to any person taking part in athletic pursuits concurrently with a trial.</p>	Insuring clauses

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
7	Add-on Cover	<<as per policy schedule>>	Policy schedule
8	Loss Participation	<<as per policy schedule>>	Policy schedule
9	Exclusions	<p>The indemnity provided does not apply to liability arising from:</p> <ol style="list-style-type: none"> 1. any claim arising from viral Hepatitis or any condition directly or indirectly caused by or associated with Human Immunodeficiency Virus (HIV I) or (HIV II), Human T-Cell Lymphotropic Virus Type 1 (HTLV I) to the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind however it may be named. However, this exclusion does not apply if the contamination can be analyzed in the retained sample of the administered biological active pharmaceutical ingredient. 2. any condition directly or indirectly caused by or associated with CreutzfeldtJakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD) 3. any circumstances which are either: a. known to the Insured at the inception of this Policy or b. likely to give rise to a claim against which the Insured would otherwise be entitled to be indemnified under more specific insurance or c. have been notified under any other insurance attaching prior to the inception of the Policy. 4. any claim arising out of any trial commencing prior to the Retroactive Date. 5. bodily injury sustained by any employee arising out of and in the course of their employment or engagement by the Insured. This exclusion shall not apply where an employee is voluntarily acting as a research subject. 6. bodily injury sustained by a research subject which was reasonably foreseeable. This exclusion shall not apply to bodily injury: a. which is intended to result from reasonable use of a drug or medical device within or upon human beings during a trial or b. which can be expected, from the standpoint of a reasonable professional conducting a trial, to result from reasonable use of a drug or device within or upon human being during a trial 7. the insolvency or bankruptcy of the Insured 8. loss of or damage to the Insured's Product(s) and costs or removal, recall, alteration, replacement or reinstatement necessitated by any defect (suspected or known) or the unsuitability for the intended purpose. 	Exclusions

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
		<p>9. punitive or exemplary damages and statutory awards of multiples of compensatory damages (i.e. treble damages).</p> <p>10. a) bodily injury, property damage, advertising injury, personal injury or denial of access arising out of the actual, alleged or threatened contaminative, pathogenic, toxic or other hazardous properties of asbestos. b) loss, cost or expense arising out of any : i. request, demand, order or regulatory or statutory requirement that any Insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of asbestos; or ii. Claim or proceeding by or on behalf of a governmental authority or others for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of asbestos.</p> <p>11. any claim, loss or damage directly or indirectly occasioned by , happening through or in consequence of terrorism, war, invasion, acts of foreign enemies, hostilities (whether war be declared or not), civil war, rebellion, revolution, insurrection, military or usurped power or confiscation or naturalization or requisition or destruction of or damage to property by or under the order of any government or public or local authority;</p> <p>12. directly or indirectly caused by or contributed to by or arising from (a) ionizing radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel (b) the radioactive toxic explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof This exclusion shall not exclude any claim directly relating to the therapeutic use of radioactivity;</p> <p>13. any claim arising out of the continued use of the drug, treatment or product under trial after the Trial has been completed and after the drug, product or treatment has been licensed in accordance with the statutory and regulatory requirements of the country in which the Trial took place;</p> <p>14. any claim arising out of or in any way connected with the alleged worsening of existing conditions or Bodily injury or new symptoms or new bodily injury of the Research Subject discontinuing existing treatment or medications for the purpose of participating in the Trial;</p>	

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
		<p>15. any claim connected with or in consequence of any service rendered by the Insured under the influence of intoxicants, narcotics or other drugs affecting neurocognitive competence.</p> <p>16. any claim arising out of or in any way connected with any bodily injury to any baby or child under the age of two years. This exclusion does not apply to a trial that has been described to us by you in the application for this insurance, to the extent that we have agreed to provide coverage in connection with such trial</p> <p>17. any claim connected to or in consequence of any damage to or change in any Research Subject's DNA or any therapy or treatment influencing Research Subject's DNA. This exclusion does not apply to a trial that has been described to us by you in the application for this insurance, to the extent that we have agreed to provide coverage in connection with such trial</p> <p>18. any claim based upon, attributable to or in any way connected with the failure of a drug, device or procedure to perform its intended purpose or function in the course of the trial;</p> <p>19. any claim arising from lack of information or insufficient information;</p> <p>20. any claim arising out of or in any way connected with any Trial undertaken without the approval of Human research ethics committee</p>	
10.	Special Conditions and Warranties (if any)	<<as per policy schedule>>	Policy schedule
11.	Admissibility of Claim	<ul style="list-style-type: none"> • Mention the broad principle of admissibility / denial of claims [Example: Reporting of loss occurrence; Duty of care & loss minimization; Exclusion of Willful Negligence] <ol style="list-style-type: none"> 1. Intimation of a claim or any circumstances which may give rise to any claim should be reported immediately. 2. No admission, offer, promise or payment of liability without Insurer consent. 3. Provide documents in support of your claims 4. Provide all such information and assistance to company which is required. 	NA

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number												
		<p>5. Company has right to defend the claim for Insured.</p> <ul style="list-style-type: none"> • Include a sample claim calculation process for retail products <p>Claim shall be paid as per following calculation:-</p> <table border="1"> <thead> <tr> <th>Head</th> <th>Example</th> </tr> </thead> <tbody> <tr> <td>liability as covered under the policy (a)</td> <td>100000</td> </tr> <tr> <td>Defense cost (b) (wherever applicable)</td> <td>20000</td> </tr> <tr> <td>total loss amount (c = a+b)</td> <td>120000</td> </tr> <tr> <td>Deductible (d)</td> <td>10000</td> </tr> <tr> <td>Net Payable amount (c-d)</td> <td>110000</td> </tr> </tbody> </table>	Head	Example	liability as covered under the policy (a)	100000	Defense cost (b) (wherever applicable)	20000	total loss amount (c = a+b)	120000	Deductible (d)	10000	Net Payable amount (c-d)	110000	
Head	Example														
liability as covered under the policy (a)	100000														
Defense cost (b) (wherever applicable)	20000														
total loss amount (c = a+b)	120000														
Deductible (d)	10000														
Net Payable amount (c-d)	110000														
12.	Policy Servicing - Claim Intimation and Processing	<ul style="list-style-type: none"> • Toll free / IVRS number of the Insurer: 120 6234 6234 / 022-6234 6234 • Website - www.hdfcergo.com Email- care@hdfcergo.com • Details of designated company officials to be contacted in time of claim Liability Claims Manager – email ID - care@hdfcergo.com • Turn Around Time (TAT) for claims settlement <ol style="list-style-type: none"> 1. Registration of claim – T +1 days 2. List of requirement – 7 days from registration 3. Claim settlement / Denial = T+30 days (T = date of receipt of last documents) • Escalation Matrix when TAT is not satisfied Email to – liabilityclaims@hdfcergo.com 	NA												
13.	Grievance Redressal and Policyholders Protection	<p>If You have a grievance about any matter relating to the Policy, or Our decision on any matter, or the claim, You can address Your grievance as follows:</p> <p>Our Grievance Redressal Officer</p> <p>If you have a grievance that you wish us to redress, you may contact us with the details of your grievance through:</p> <ul style="list-style-type: none"> • Call Centre - 120 6234 6234 / 022-6234 6234 • Emails – grievance@hdfcergo.com • Contact Details for Senior Citizens: 022 6242 6226 Email ID: seniorcitizen@hdfcergo.com Designated Grievance Officer in each branch. 	Grievances												

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
		<ul style="list-style-type: none"> • Company Website – www.hdfcergo.com • Courier - Any of our Branch office or corporate office <p>You may also approach the Complaint & Grievance (C&G) Redressal Cell at any of our branches with the details of your grievance during our working hours from Monday to Friday.</p> <p>If you are not satisfied with our redressal of your grievance through one of the above methods, you may contact our Head of Customer Service at</p> <p style="text-align: center;">The Complaint & Grievance Redressal Cell, HDFC ERGO General Insurance The Company Ltd. D-301, 3rd Floor, Eastern Business District (Magnet Mall), LBS Marg, Bhandup (West), Mumbai – 400078, Maharashtra</p> <p>In case you are not satisfied with the response / resolution given / offered by the C&G cell, then you can write to the Chief Grievance Officer of the Company at the following address</p> <p style="text-align: center;">To the Chief Grievance Officer HDFC ERGO General Insurance The Company Limited D-301, 3rd Floor, Eastern Business District (Magnet Mall), LBS Marg, Bhandup (West), Mumbai - 400078, Maharashtra e-mail: cgo@hdfcergo.com</p> <p>Grievance may also be lodged at IRDAI Integrated Grievance Management System- https://bimabharosa.irdai.gov.in</p> <p>You may also approach the nearest Insurance Ombudsman for resolution, if your grievance is not redressed by the Company. The contact details of Ombudsman offices are below if your grievance pertains to:</p> <ul style="list-style-type: none"> • Insurance claim that has been rejected or dispute of a claim on legal construction of the policy • Delay in settlement of claim • Dispute with regard to premium • Non-receipt of your insurance document <p>You may also refer Our website www.hdfcergo.com https://www.hdfcergo.com/customer-voice/grievances for detailed grievance redressal procedure.</p>	

SI No	Title	Description (Please refer to applicable Policy Clause Number in next column)	Policy / Clause Number
14.	Obligations of the Policyholder	<ul style="list-style-type: none"> • To disclose all information correctly sought by the insurer at time of filling the proposal form • In case of any change / modification / addition to the already declared information the same shall be brought to the notice of the Insurer immediately • Non-disclosure of material information may affect the claim settlement. <p>Disclosure of other material information during the policy period.</p>	NA

Declaration by the Policy Holder:

I have read the above and confirm having noted the details.

Place: _____

Date: _____

(Signature of the Policyholder)

Note:

- i. In case of any conflict, the terms and conditions mentioned in the policy document shall prevail.