



# Institutional Ethics Committee Of

## KLE Academy of Higher Education and Research

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### **FORM NO: 17-CLINICAL TRIAL AGREEMENT ASSESSMENT FORM - LEGAL EXPERT**

IEC Protocol Code		Principal Investigator	
Protocol Version and date		Meeting Date and Time	

#### **Name and Designation of Reviewer:**

Sl. No	Description	Yes	No
1.	Effective date		
2.	Parties Involved		
	Tripartite		
	Quadra parted		
3.	Agreed terms - Definition, Conduct of the study, Responsibility of the company, Principal investigator, Institution		
4.	Study drug and Materials		
5.	Payment Details- Budget and Payment scheduled, payment schedule, Payment terms, Reimbursement, Payment for screen failure, payment for study coordinator.		
6.	Confidentiality of the study participants		
7.	Publications		
8.	Representations, warranties and covenant.- Of the PI, Of the Sponsor, No other Representations or warranties, Of the Institutions		
9.	<b>Governing Law</b> -This agreement and any dispute or claim out of or in connections with it or its subject matter (including non- contractual disputes or claims) shall be governed by and constructed in accordance with the laws of India without regard to the conflict of law principles thereof. The parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject		
10.	Indemnification - Sponsor Indemnification, Institution Indemnification, Notification, Claims, Representation, subject injury.		
11.	Insurance - Sponsor insurance, Site Insurance		
12.	Compliance, Transparency, Anti - bribery, Anti- corruption and Conflict of Interest.		
13.	Term and Termination		
14.	Agreed by the parties - Sponsor/ CRO, PI, Institution, SMO( if involved)		
15.	Witness details		

**Date and sign of the reviewer**