

Institutional Ethics Committee



KLE Academy of Higher Education and Research
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FORM NO: 30 STUDY ASSESSMENT FORM FOR AMENDED PROTOCOL

IEC prot	cocol Code			
Name of	f Principal Investigator			
Protoco	l Version & Date			
Reviewe	er's name with Designation:			
Meeting	Date (D/M/Y):			
	Mark and comment on whatever items a	pplicable to the stu	dy	
Sl. No	Particulars	Appropriate	Inappropriate	NA
Details of Amended Protocol (If Applicable)				
1.	Summary of Changes			
2.	Inclusion Criteria			
3.	Exclusion Criteria			
4.	Vulnerability assessment (If Applicable)			
5.	Analysis of types of samples			
6.	DCGI submission/Approval Letter if Applicat	ole		
Particip	pant Information Sheet and Informed Conse	nt Documents		
1.		back		
	translation certificates			
2.	Language of the ICD: Kannada, Hindi, English Marathi	and		
3.	Risks and Benefits			
4.	Period of storage of biological samples if Any			
5.	Privacy & Confidentiality			
6.	Provision for Compensation per subjects in ITA(INR)	CFs-		
	Reviewer Sig	gnature		•