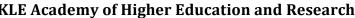


Institutional Ethics Committee









FORM NO: 42

CHECKLIST FOR IEC MEMBERS STUDYMONITORING VISIT

Type of Monitoring [$$ }						
For Cause			Routine			
 a) High number of protes b) Large number of protes researcher; c) Large number of SAI d) High recruitment rate e) Complaints received f) Non-compliance with g) Misconduct by the researcher; h) Any other cause as defined 	Randomly					
IEC protocol Code	Protocol and Study team d	Date of visit				
PI Name		Site ID				
Study CRCs		Phone No:				
CROs/Sponsors Name	and contact details					
Participants Details						
Screened:		Ongoing:				
Enrolled:		completed				
Drop out:		Follow up				
Awareness of the rights [Y/N]-Comments		Subject interview (if planned)				
Satisfied with the pro	cess					
Study protocol and its related information						
Use of recent (IEC approved) version of protocol						
Use of recent (IEC approved) version of informed						
consent document						
Informed consent process complete (including source						
documentation)						
Is the delegation proper (as respect to qualification and						
experience)						



Institutional Ethics Committee



KLE Academy of Higher Education and Research (Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India) KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State India (: 0831-2470400 www.kledeemeduniversity.edu.inE mail:kleclinicalresearch@gmail.com

SAE reporting timely and complete (if any)				
Weather appropriate vernacular consent have been				
taken				
Investigational Medicinal Products				
Logs up to date				
Safekeeping with controlled access and temperature				
maintenance				
Clear delegation				
Ethical concerns:				
Grievance handling explained and the same documented				
Subject/s remuneration done as due				
Is there any involvement of vulnerable population (if Yes				
Please write the type of Vulnerability)				
Is the study team conducting repeated				
education/information about research, benefits, risks				
and alternatives for vulnerable persons?				
Justification for the inclusion of vulnerable population in				
the research				
Note: Corrective and preventive action submitted by PI Within 15days of the recipient				

Study status: Enrolling/Follow up/Data cleaning:



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I. MONITORING-SUMMARY:

	Study stat	us details					
Screened:		Ongoing:					
Enrolled:		completed					
Drop out:		Follow up					
CROs/Sponsors Name		L					
Study participants status and Details:							
Screened:	Enrolled:	Ong		going:			
Drop out:	Completed:	AE/		/SAE:			
Key Dates							
IEC Approval	Study initiation		Firs	First Participant screened			
	4						
Essential documents latest versions and date:							
Protocol	ICD		Investigator Brochure				
		>					
Qualification, ICH-	Co-Investigator		Stuc	ly CRCs			
GCP training etc.,							
II. Documents Reviewed:							
Signed Informed	Consents:						
Source Documer	nts:						
☐ Monitoring/ aud	liting reports:						
☐ Investigational F	Product use, storage & r	reconciliation reco	rds:				
Delegation of Re	sponsibilities Log:						
Subject Enrolme	nt Log (equitable distri	ibution):					
Clinical trial Agr	eement, Indemnity & Ir	nsurance:					
☐ Investigator's Fi	le & Communications fi	ile					
III. <u>If any suggestions:</u>							
IEC Administrator/Mombor Socretary Signature							

IEC Administrator/Member Secretary Signature