Institutional Ethics Committee
Of
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

FORM NO: 42

CHECKLIST FOR IEC MEMBERS STUDYMONITORING VISIT

Type of Monitoring [√]	
For Cause	**Routine**
a) High number of protocol violations/ deviations b) Large number of proposals carried out at the study site or by the same researcher; c) Large number of SAE reports; d) High recruitment rate; e) Complaints received from participants; f) Non-compliance with EC directions g) Misconduct by the researcher; and h) Any other cause as decided by the EC	Randomly

Protocol and Study team details			
IEC protocol Code		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 process			

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)	

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 status details			
Screened:		Ongoing:	
Enrolled:		completed	
Drop out:		Follow up	
CROs/Sponsors Name			
Study participants status and Details:			
Screened:	Enrolled:		Ongoing:
Drop out:	Completed:		AE/SAE:
Key Dates			
IEC Approval	Study initiation		First Participant screened
Essential documents latest versions and date:			
Protocol	ICD		Investigator Brochure
Qualification, ICH-GCP training etc.,	Co-Investigator		Study CRCs

II. Documents Reviewed:

- ☐ Signed Informed Consents:
- ☐ Source Documents:
- ☐ Monitoring/ auditing reports:
- ☐ Investigational Product use, storage & reconciliation records:
- ☐ Delegation of Responsibilities Log:
- ☐ Subject Enrolment Log (equitable distribution):
- ☐ Clinical trial Agreement, Indemnity & Insurance:
- ☐ Investigator's File & Communications file

III. If any suggestions:

IEC Administrator/Member Secretary Signature