



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

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FORMS:14 PART-A: STUDY ASSESSMENT FORM INDEPENDENT CONSULTANT

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

Name of the independent Consultant with Designation:

Sl. No	Particulars	Appropriate	Not Appropriate	N/A	Comments
1.	Scientific related issues				
	Rationale				
	Objectives				
	Study design				
	Study population				
	Sample size				
	Inclusion Criteria				
	Exclusion Criteria				
	Withdrawal criteria				
	Procedures used in research				
	The use of placebo				
	The use of medical device				
	Method of Research Assessment - Assessment of efficacy - Assessment of safety				
	Monitoring Complications and solutions				
	Blood or specimens [Frequency & Amount]				
Duration and number of follow up					
Static used in analysis					
2.	Ethical issues				
	Involvement of Vulnerability				
	- Identification of Vulnerability - Justification for the use of Vulnerable population - Protection of Vulnerable groups				
	Risk to the health of participants				
	- Identify the risk: physical, psychological, economic, legal risk or risk due to invasion of privacy and confidentiality				
	Sufficient measures to prevent or minimize the risks				
	Risk to the health of the embryo or the unborn child or spouse				
	Risk to the research community				
	Direct benefits to participants -During and after the study				
	Benefits to Society				



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	Favorable benefits/risk ratio				
3.	Qualification of Investigator				
	Expertise of investigator(s)				
	Training of the investigator(s) (GCP for clinical trials or Human Participant Protection)				
	Conflict of interest of the investigator(s)				

For medical device protocols:

Non-significant risk	Significant risk
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Risk assessment of the protocol: Put Tick ✓ Mark

Research not involving more than minimal risk	
Research involving greater than minimal risk but presenting the prospect of direct benefit to the participants	
Research involving greater than minimal risk and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition	

Duration of progress report:		
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Opinion of the Reviewer:

Approve with or without suggestions	
Minor Modification	
Major Modification	
Disapprove	

Reviewer Name signature and date