

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

FORM NO: 16-STUDY ASSESSMENT FORM FOR NEW PROTOCOL PART-A- Medical Scientist

IEC Protocol Code	055-2023	Principal Investigator	Dr.Jayaprakash A
Protocol Version and date	00 -18-Jun-2023	IEC Meeting Date and Time	28-Dec-23 @3:30 PM

Primary Reviewer's name with Designation:

	Reviewer's name with Designation:	Т	T	1	_		
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						



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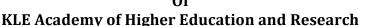
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	Direct benefits to particip	ants					
	-During and after the stud	dy					
	Benefits to Society						
	Favorable benefits/risk r	atio					
3.	Qualification of Investig	gator		1	•		
	Expertise of investigator((s)					
	Training of the investiga	ator(s) (GCP					
	for clinical trials or Human						
	Participant Protection)						
	Conflict of interest	of the					
	investigator(s)						
For medical device protocols:							
	Non-significant risk Significant risk						
Risk asse	essment of the protocol: P	ut Tick√Mark					
Research	n not involving more than r	ninimal risk					
Research involving greater than minimal risk but presenting the prospect of direct benefit to the participants						to the	
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							
	<i>y</i>	J					
Duratio	n of progress report:	06 -Months			12 Months		
Opinion of the Reviewer:							
Approve							
Minor M	Iodification						
Major M	odification						
Disappr	ove						

Reviewer Name signature and date



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FORM NO: 16-STUDY ASSESSMENT FORM FOR NEW PROTOCOL PART-B-LAYPERSON

IEC Protocol Code	055-2023	Principal Investigator	Dr.Jayaprakash A
Protocol Version and date	00 -18-Jun-2023	IEC Meeting Date and Time	28-Dec-23 @3:30 PM

Primary Reviewer's name with Designation: Sl. No Particulars **Appropriat** Not N/A Comment **Appropriate** 1. Informed consent issues Objective of the research Voluntary Right to withdraw from the study Alternatives in case of non-participation Rationale of the study Study procedure and participant's responsibilities Risks or discomforts to the participants Benefits to the participants or others Medical care during the study Payment/reimbursement/compensation Privacy and confidentiality Name, contact address, and telephone number of the Investigator Contact address and telephone number of the ethics committee Certificate of informed consent form/Assent form Language used in the informed consent form Format of informed consent form 2 Sign of LAR/Subject/Impartial Witness/PI and study team details Copy of the Patient Information sheet with duly filled ICF shall be handed over to the subject or his or her attender Reviewer Name signature and date