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: 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:

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				
	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

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:	**06**-Months	**12** Months

Opinion of the Reviewer:

Approve	
Minor Modification	
Major Modification	
Disapprove	

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	Appropriate	Not Appropriate	N/A	Comment
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				
2	**Format of informed consent form**				
	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				