

# Institutional Ethics Committee Of KLE Academy of Higher Education and Research

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## **FORM NO: 26 IEC APPROVAL LETTER TEMPLATE**

To

Dr.

Dear Dr. \_\_\_\_\_

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate)

IEC protocol Code:

Name of the sponsor or CRO:

reviewed and discussed your application to conduct the clinical trial entitled "....." on.....(date).

The following documents were reviewed:

- a. Trial protocol (including protocol amendments), dated.....version No.(s) .....
- b. Patient information sheet and informed consent form (including updates, if any) in English or vernacular language version..... And..... date
- c. Investigator's brochure, dated ....., Version no..... Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.
- d. Principal investigator's current Curriculum Vitae.
- e. Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.
- f. Investigator's agreement with the sponsor.
- g. Investigator's undertaking
- h. Clinical trial agreement
- i. Other documents

The following members of the ethics committee were present at the meeting held on (date, time, place).

.....Chairperson of the ethics committee;

..... Member-Secretary of the ethics committee;

..... Name of each member with designation;

Conflict of Interest: Yes/No

Approval Period: ONE Year

### **IEC Decision:**

<b>1</b>	Approved with or without suggestions	
<b>2</b>	Minor modifications	
<b>3</b>	Minor modifications for resubmission	
<b>4</b>	Disapproved	

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided.

Progress of the study periodically [Biannual\* and/or Annual report]

During the course of this investigation, any significant deviations from the approved protocol and/or serious adverse events should immediately brought to the attention of the Ethics Committee  
Submit the continuing letter at least 2 months prior to the end of -the approval period

Yours sincerely,

Member Secretary, Ethics Committee