



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

t: 0831-2470400 www.kledeemeduniversity.edu.in mail:kleclinicalresearch@gmail.com



FORM NO: 22-GUIDANCE OF PROTOCOL SUBMISSION

The IEC is currently following the V-8.5 dated Mar-2023 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 in number.

The SOPs are available on the institutional Ethics Committee institute website and 02 no's hard copies available at IEC of KAHER office.

The templates and forms are available on the Institute website [Institutional Ethics Committee KAHER - KLE Academy of Higher Education and Research \(kledeemeduniversity.edu.in\)](http://www.kledeemeduniversity.edu.in) for submission to the Institutional Ethics Committee of KLE Academy of Higher Education and research, Beagavi-10

I. Prior to approval of a research study:

- Submission of a New Study Proposal
 - › PI/study designee Submission of ethics committee dossier to IEC office/secretariat- within **21** days
 - › The secretariat sends the copies to the IEC members at least **14 days** in advance of the full board meeting.
 - › The protocol will be reviewed at the scheduled IEC full board meeting
 - › An investigator is expected to be present at the time of full board meeting and will be invited (telephonically and/or mail) to the IEC meeting to discuss issues study proposal.
 - › After the full board, the approval letter will be given within **07 working days**.
 - › Within 90 days after the letter's receipt, an investigator is required to respond to the IEC's letter of recommendations and queries. The principal investigators will get two reminders prior to 90 days. If there is no response. The protocol will be committed as a new submission.

II. Once approval for a study is granted

- › An approval will be granted for usually one-year study period.
- › It is the responsibility of the principal investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 2 months of the due date i.e. 10 months from the date of approval)



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- › Submission of Study Related Documents for IEC review or notifications.
- › Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations or any other notifications) would be accepted during the office hours. Two set of the above stated study related documents need to be submitted for the IEC review/notification as per the format and one copy will be returned to after being acknowledged by the member secretary/Chairperson/or IEC secretariat.

No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants