



**Institutional Ethics Committee
Of**

KLE Academy of Higher Education and Research

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FORM NO: 50

AUDIT AND INSPECTION CHECKLIST

Internal Audit External Audit Regulatory Inspection	Date:
The date(s) which the audit/inspection has been agreed for:	
Review the SOPs and note details of any omissions or deviations, with reasons	
Check the files for the presence of all signed documents. Note any that are missing and actions taken. <ul style="list-style-type: none"> > Background and training records of EC members > Application Submission Records > Protocol Assessment Records > Communication Records > Amendment Approval > Meeting Agenda, Minutes, Approval letters > Active files > Continuing and Final reports 	
Are any documents known to be missing from the study master file?	
Which personnel and members will be available? Give details of times and dates.	
What arrangements are there in the event the auditor/inspector needs to make copies of documents?	
Completed by: Name and Signature	Date: