

**ANNEXURE: 01**

**AF/IEC/01/24/V7.1**

**Audit and Inspection Checklist**

<input type="checkbox"/> Internal Audit <input type="checkbox"/> External <input type="checkbox"/> Audit/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"> <li>✓ Background and training records of IEC members</li> <li>✓ Application Submission Records</li> <li>✓ Protocol Assessment Records</li> <li>✓ Communication Records</li> <li>✓ Amendment Approval</li> <li>✓ Meeting Agenda, Minutes, Approval letters</li> <li>✓ Active files</li> <li>✓ Continuing and Final reports</li> </ul>	
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:.....

**Confidentiality Agreement Form for Auditors/inspectors**

I, \_\_\_\_\_ from \_\_\_\_\_ as an **Auditors/inspectors** of Ethics Committee KLE University for Clinical Studies, understand that the copy (ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Ethics Committee and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IEC documents:

.....  
.....  
.....

\_\_\_\_\_  
Signature of the recipient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Member Secretary,

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairman of IEC, Belagavi

\_\_\_\_\_  
Date