20.1. Purpose

The purpose of this SOP is to guide an Institutional Ethics Committee (IEC) to prepare for an audit or inspection of the IEC.

20.2. Scope

The SOP applies to all the IEC members and the Secretariat.

20.3. Responsibility

It is the responsibility of the Member Secretary, Chairperson, IEC Members and the IEC Secretariat to keep IEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

20.4. Definitions and Mandate

20.4.1 Definitions

- **Audit:**

  I. A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP),and the applicable regulatory requirement(s).

  II. Audit of a Trial- A systematic verification of the study, carried out by persons not directly involved, such as:

  (a) Study related activities to determine consistency with the Protocol

  (b) Study data to ensure that there are no contradictions on Source Documents. The audit should also compare data in the Source Documents with the interim or final report. It should also aim to find out if practices were employed in the development of data that would impair their validity.

  (c) Compliance with the adopted Standard Operating Procedures (SOPs).

- **Inspection:**

  An official review/ examination conducted by regulatory authority/ authorities of the documents, facilities, records and any other resources that are deemed by the

authority/ authorities to be related to the study. The inspection may be carried out at the site of the trial, at the sponsor's / or CRO's facilities and Ethics Committee in order to verify adherence to Good Clinical Research Practice.

20.4.2 Mandate

Clause 29. 'Inspection of premises relating to clinical trial in its gazette notification GSR 227(E) dated 19.3.2019 states. 'The person or the institution or the organisation permitted to conduct clinical trial under rule 22 in Form CT-06 or rule 23 in Form CT -4A including his representatives and investigator, shall allow any officer authorised by the Central Licensing Authority, who may, if considered necessary, be accompanied by an officer authorised by the State Licensing Authority, to enter the premises and clinical trial site with or without prior notice to inspect, search or seize, any record, statistical result, document, investigational drug and other related material; and reply to queries raised by the inspecting authority in relation to conduct of such clinical trial.'

20.5. Detailed instructions

20.5.1 Receipt of notification of an Audit / Inspection

On receipt of written/ mailed communication regarding audit/ inspection visit, the Member Secretary will inform the Chairperson, IEC members and the Head of Institution, about the date and purpose of the audit/inspection.

20.5.2 Preparing for the audit

- On receiving information about the audit /inspection, IEC Member Secretary and/or IEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and/or designated IEC member/s will make arrangements in accordance with the steps mentioned in the checklist.
- The studies with incomplete/missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

20.5.3 on the day/s of Visit

- Chairperson / Member Secretary / designated IEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information needed.
- The IEC Chairperson/Member Secretary/IEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/ designated IEC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

20.5.4 Correction of deficiencies observed at audit/ inspection

- Member Secretary/designated IEC member/ Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/Inspection Report the Chairperson should implement corrective and preventive actions and set the timeline for implementation of corrections as stated by the auditor/inspector.
- Action plan should be communicated by the Member Secretary/designated IEC member to the auditor/inspector after seeking approval of the Chairperson.
- A review date for an internal follow-up audit will be decided by the Chairperson (if applicable).
- The Member Secretary/ designated IEC member should report the outcome of the internal follow-up audit to the Chairperson.

5.5 Recording the Audit/Inspection Visit

- The Member Secretary, designated IEC member and the Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.
- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

6. Annexure 1: AX 01/SOP 20/V1 - Audit and Inspection Checklist

Annexure: AX 01/SOP 20/V1

Audit and Inspection Checklist

1. Date of letter of communication regarding audit/inspection:
2. Date(s) on which the audit/inspection has been agreed on:
3. To ensure the IEC members and staff have been informed about the date/s and time.
4. To ensure availability of IEC related information – mandate, terms of reference, organisation chart (in the print form) in the IEC office.
5. To make sure of availability of latest copy/copies of signed SOPs in print form in the office and/or in electronic form on the IEC computer/s.
6. To review the SOPs and note details of any omissions or deviations, with reasons.
7. To ascertain availability of all national and international ethics guidelines and regulations in print form and/or in electronic form in the IEC office.
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken.
    - Records regarding applications of research studies for review including protocols and related documents
    - Record of Protocol Assessment Forms – Comments of IEC members, Meeting Agenda,
    - Minutes (documented in individual study file or separately as meetings file)
    - Communication records with investigator (documented in individual study file)
    - Amendment Approvals (documented in individual study file)
    - SAE reports and SAE related communications with investigator and regulators.
    - Protocol deviation/violation/exception reports (documented in individual study file)
    - Continuing and final completion/termination reports (documented in individual study file)
9. To ensure availability of documents regarding list of members, appointment details like tenure, CVs, baseline and periodic training of IEC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.

11. To ensure measures for maintaining security of electronic database and office records.
12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files is done as per the respective SOPs.
13. To ascertain proper labelling and indexing of study files and storage cabinets.
14. To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up internal audit (if applicable)
15. To report to IEC members at the full committee meeting about findings in the audit/inspection report received.
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

20.7. Flow Chart

No.	Activity	Responsibility
1	Receipt of Audit/ Inspection notification	IEC Member Secretary
2	Preparing for the audit	IEC Member Secretary/ designated IEC member/ Secretariat
3	Presenting information and files to auditor/ inspector	IEC Member Secretary/ designated IEC member/Secretariat
4	Review comments/ recommendation of auditor/ inspector	IEC Member Secretary/ designated IEC member/Secretariat
5	Receipt of audit/ inspection report	IEC Member Secretary/ designated IEC member
6	Planning corrective/preventive actions and setting timeline for their implementation	IEC Chairperson
7	Conducting internal follow-up audit	IEC Member Secretary/ designated IEC member
8	Recording the Audit/Inspection Visit	IEC Member Secretary/ Secretariat