Title: Preparing for Ethics Committee Audit/ Inspection

SOP Code: SOP 01/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

Prepared by:

Dr. Padmaja Marathe, FERCI Member	(Signature with Date)

Reviewed by:

Dr. U. M. Thatte, FERCI Secretary	(Signature with Date)
Dr. S. K. Kamat, FERCI Treasurer	(Signature with Date)

Approved by:

Dr. Vasantha Muthuswamy, FERCI President	(Signature with Date)
Dr. Nandini Kumar, FERCI Vice President	(Signature with Date)

Table of Contents:

1. Purpose

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

2. Scope

The SOP applies to all the IEC members and theSecretariat.

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.

4. Definitions and Mandate

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). [*http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015*]

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 on 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).

[*http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Nov 2015*]

- **Inspection:**

  An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) 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. [*http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015]*

  [http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Nov 2015]

4.2 Mandate

- The Drugs Controller General India (DCGI) in its gazette notification GSR 72E, dated 08th February 2013, 122DD states, 'The Ethics Committee shall allow inspectors of officials authorised by the Central Drugs Standard Control Organisation to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of the trial.'

5. Detailed instructions

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, if applicable about the date and purpose of the audit/inspection.

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.(*AX 01/SOP 20/V1*)
- 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.

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 is 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.

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 measures 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/ 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

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

Annexure 1: 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
    - Protocol Assessment Records – Comments of IEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records 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, tenure, appointment details, 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 are 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 audit(if applicable)
15. To report about findings and report received regarding audit/inspection to IEC members at the full board IEC meeting.
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

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