Title: Preparing for Ethics Committee Audit/ Inspection

1. Purpose

The purpose of this SOP is to guide SMVMCH-EC to prepare for an audit or inspection of the EC.

2. Scope

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

3. Responsibility

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

4. Detailed instructions

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 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

- On receiving information about the audit /inspection, EC Member Secretary and/ or EC member/s are given the responsibility by the Chairman to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and / or designated EC member/s will make arrangements in accordance with the steps mentioned in the checklist.(*AX 01/SOP 20/V4*)
- 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.

4.3 On the day/s of Visit

- Chairman / Member Secretary / designated EC 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 EC Chairman / Member Secretary / EC 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 EC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

4.4 Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated EC member/ Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/ Inspection Report the Chairman 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 EC member to the auditor/inspector after seeking approval of the Chairman.

A review date for an internal follow-up audit will be decided by the Chairman (if applicable).

The Member Secretary/ designated EC member should report the outcome of the internal follow-up audit to the Chairman

4.5 Recording the Audit/Inspection Visit

- The Member Secretary/ designated EC 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.

5. References to other applicable SOP – NIL

6. Annexure

Annexure 1:*AX 01/SOP 20/V4*- Audit and Inspection Checklist

Annexure 1: AX 01/SOP 20/V4
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 EC members and staff have been informed about the date/s and time.
4. To ensure availability of EC related information – mandate, terms of reference, organisation chart (in the print form) in the EC 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 EC 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 EC 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 EC members, Meeting Agenda Minutes (documented in individual study file or separately in meeting records file)

- o Communication records with investigator (documented in individual study file)
- o Amendment Approvals (documented in individual study file)
- o SAE reports and SAE related communications with investigator and regulators
- o Protocol deviation/violation/exception reports(documented in individual study file)
- o 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 EC 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 EC members at the full board EC 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	Member Secretary
2	Preparing for the audit	Member Secretary/ designated IEC member/ Secretariat
3	Presenting information and files to auditor/ inspector	Member Secretary/ designated IEC member/ Secretariat
4	Review comments/ recommendation of auditor/ inspector	Member Secretary/ designated IEC member/ Secretariat
5	Receipt of audit/ inspection report	Member Secretary/ designated IEC member
6	Planning corrective/preventive actions and setting timeline for their implementation	Chairperson
7	Conducting internal follow-up audit	Member Secretary/ designated IEC member
8	Recording the Audit/Inspection Visit	Member Secretary/ Secretariat

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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