Annexure 27

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, organization 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 member secretary

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 labeling 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.