

Title: Preparing for Yenepoya University Ethics Committee Audit/ Inspection

SOP Code: SOP20/v2

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1. Purpose

The purpose of this SOP is to guidelines for Yenepoya University Ethics Committee (YUEC) to prepare for an audit or inspection.

2. Scope

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

3. Responsibility

It is the responsibility of the Member-Secretary, Chairperson, YUEC Members and the YUEC Secretariat to keep 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:

4.1.1 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)¹.

4.1.2 Audit of a Trial²: A systematic verification of the study, carried out by persons not directly involved, such as:

- Study related activities to determine consistency with the protocol
- 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.
- Compliance with the adopted Standard Operating Procedures (SOPs).

¹ http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 12 July 2016 at 2338 hours.

² <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 12 July 2016 at 2342 hours

Inspection:

4.1.3 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 the Secretariat of YenePOYA University Ethics Committee in order to verify adherence to Good Clinical Research Practice^{3,4}.

4.2 Mandate:

4.2.1 Drugs Controller General India (DCGI) in its gazette notification GSR 72E, dated 08th February 2013, 122DD states 'The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization 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.

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, YUEC members and the Head of Institution, if applicable about the date and purpose of the audit/inspection

5.2 Preparing for the audit

5.2.1 On receiving information about the audit/inspection, YUEC Member Secretary and/or YUEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.

5.2.2 The Member Secretary and/or designated YUEC member/s will make arrangements in accordance with the steps mentioned in the checklist.

³ http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 12 July 2016 at 2344 hours

⁴ <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 12 July 2016 at 2346 hours

⁵ <http://www.cdsco.nic.in/writereaddata/YENEPOYA%20RC.pdf> accessed on 12 July 2016 at 2355 hours.

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5.2.3 The studies with incomplete/missing documents will be dealt with separately and actions taken will be documented.

5.2.4 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 the visit/audit/inspection:

5.3.1 Chairperson/Member-Secretary/designated YUEC member(s) should welcome and accompany the auditors/inspectors to the reserved meeting room.

5.3.2 Designated team members must be present in the meeting room.

5.3.3 The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.

5.3.4 The YUEC Chairperson/Member-Secretary/YUEC members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.

5.3.5 The information and files requested by the auditors/inspectors should be made available by the Secretariat.

5.3.6 The Member-Secretary/designated YUEC member/Secretariat will make note of the comments, recommendation of the auditors/inspectors.

5.4 Corrections of deficiencies observed at the audit/inspection

5.4.1 Member-Secretary/designated YUEC member/Secretariat will review comments and recommendations of the auditor/inspector.

5.4.2 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.

5.4.3 Action plan should be communicated by the Member Secretary/ designated YUEC member to the auditor/inspector after seeking approval of the Chairperson.

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

5.4.5 The Member Secretary/designated YUEC member should report the outcome of the internal follow-up audit to the Chairperson

5.5 Recording the audit/visit/inspection:

5.5.1 The Member-Secretary/designated YUEC member/Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.

5.5.2 The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

6. Annexures

Annexure 1: *Ann01/SOP20/v2- Audit and Inspection Checklist*

Annexure 1: Ann01/SOP20/v2 Audit and Inspection Checklist

Sl.No	Checklist item	Check if completed
1	Date of letter of communication regarding audit/inspection	
2	Date(s) on which the audit/inspection has been agreed on	
3	Communication to ensure YUEC members and staff have been informed about the date(s) and time	
4	Chairperson designates Member-Secretary/YUEC member as coordinator	
5	Ensure availability of YUEC related information: mandate, terms of reference, organization chart (in the print form) in the YUEC Secretariat	
6	Ensure availability of latest copy/copies of signed SOPs in print form in the office and/or in electronic form on the YUEC Secretariat computer(s)	
7	Review the SOPs and note details of any omissions or deviations, with reasons	
8	Ascertain availability of all national and international ethics guidelines and regulations in print form and/or in electronic form in the YUEC Secretariat	
9	Check files of ongoing and complete research studies for the presence of all signed documents as stated below and to note any missing/incomplete documentation and actions taken: <ul style="list-style-type: none"> ➤ Records regarding applications of research studies for review including protocols and related documents ➤ Protocol Assessment Records – Comments of YUEC members, meeting, agenda, minutes (documented in individual study file or separately) 	

	<p>in meeting records file)</p> <ul style="list-style-type: none"> ➤ 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) 	
10	Ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of YUEC members	
11	Ensure availability of documents regarding appointment, CVs and training of staff of secretariat	
12	Ensure measures for maintaining security of electronic database and office records	
13	Ensure maintenance, retrieval, storage, archival and tracking of study files are done as per the respective SOPs	
14	Ascertain proper labeling and indexing of study files and storage cabinets	
15	Decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up audit(if applicable)	
16	Report about findings and report received regarding audit/inspection to YUEC members at the subsequent YUEC meeting	
17	Make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable	
18	Ensure the fees (if applicable) are paid and receipt obtained	
19	Post visit, Member-Secretary to ensure that the compliance report is submitted on time	

7. Flow Chart

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