

**Title: Preparing for Audit/ Inspection of YenePOYA Ethics Committee- 1**

**SOP Code:** SOP20/v3

**Effective Date:** 03/10/2019

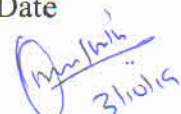
**Prepared by:**

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date  3/10/2019
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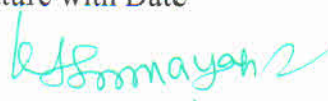
**Reviewed by:**

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**Approved by:**

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  3/10/19
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**Notified by:**

Registrar, Yenepoya deemed to be University	Signature with Date  3/10
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**1. Purpose:**

The purpose of this SOP is to describe how YEC-1 should prepare for, conduct itself in and respond to an audit or an inspection of YEC-1

**2. Scope:**

The SOP applies to any audit of the YEC-1 that may be conducted by an authorized agency internal to Yenepona deemed to be University or any authorized external agency like regulatory authorities, accreditation bodies, etc.

**3. Responsibility:**

**3.1. YEC-1 Chairperson will:**

- 3.1.1. designate the Member-Secretary (as coordinator) and/or one or more YEC-1 members to take responsibility of preparing for the audit/inspection
- 3.1.2. encourage the YEC-1 members to take part in the audit/inspection responsibly and professionally
- 3.1.3. welcome the auditing/inspecting team and facilitate smooth conduct of the audit/inspection
- 3.1.4. ensure timely preparation of the YEC-1 response to the audit/inspection report and approve the same
- 3.1.5. approve the corrective action if any deficiencies found as per the recommendation in the audit/inspection report
- 3.1.6. plan an internal follow-up audit in order to verify the changes implemented ( if applicable).

**3.2. YEC-1 Member-Secretary will:**

- 3.2.1. receive the details of audit/inspection from the auditors/inspectors and acknowledge
- 3.2.2. communicate the details of the proposed audit to the Chairperson, YEC-1 members and the University

- 3.2.3. communicate and coordinate with the concerned persons, and make logistic arrangements for the visit of the auditors/inspectors
  - 3.2.4. study the requirement for the audit/inspection and prepare accordingly
  - 3.2.5. keep the documents and office ready for the audit/inspection
  - 3.2.6. inform the concerned principal investigators and the concerned hospital authorities to keep the trial sites prepared if site visit by the auditors/inspectors is expected or scheduled
  - 3.2.7. prepare and submit the response of the YEC-1 to the audit/inspection report in a timely manner
  - 3.2.8. prepare the corrective action report as per the deficiencies listed in the audit report.
- 3.3. **YEC-1 Member(s) will:**
- 3.3.1. assist the Member-Secretary/Coordinator during the preparation for the audit, if so assigned by the Chairperson.
  - 3.3.2. take responsibility of the preparation for the audit/ inspection is designated by the Chairperson.
  - 3.3.3. be present at the time of audit/inspection
  - 3.3.4. take part in the interview and meeting with the audit/inspection team
- 3.4. **YEC-1 Secretarial staff will:**
- 3.4.1. assist the Member-Secretary to keep documents ready for audit and be available to answer questions during audit or inspection by administrative and regulatory authorities.
- 3.5. **University authorized representative will:**
- 3.5.1. make themselves available to attend the opening and closing (debriefing) meetings convened by the auditors/inspectors

#### 4. Definitions:

- 4.1. **Audit:** A systematic and independent examination of the overall functioning of the Yenepoya Ethics Committee - 1, through examination of the documents, assessing the processes and infrastructure, interacting with YEC-1 members and researchers, and observing the YEC-1 meeting(s), to determine whether the review and approval activities are being conducted, data recorded and accurately reported as per current guidelines and regulatory requirements.
- 4.2. **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 a human research 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 Ethics Committee- 1 in order to verify adherence to Indian Good Clinical Practice guidelines, with a rider that this SOP lays down responsibilities only for the inspection of YEC-1
- 4.3. **Audit of a Trial:** A systematic verification of the study (carried out by persons not directly involved) such as:
- 4.3.1. Study related activities to determine consistency and concordance with the approved protocol
  - 4.3.2. Study data to ensure that there are no contradictions on source documents.
  - 4.3.3. Comparison of data on the source documents with the interim or final report. Assessment of practices employed in the development of data and whether this would impair the validity of the data.
  - 4.3.4. Compliance with the adopted Standard Operating Procedures (SOPs).

5. **Mandate:** The Drugs Controller General India (DCGI) or any other authority so

empowered/delegated by the current rules & regulations, can request an audit/inspection. In addition, YEC-1 may invite quality assessors/surveyors to perform a quality assessment exercise. Yenepoya Ethics Committee - 1, shall allow inspectors or officials authorized by the Government of India, or any assessors of accreditation, or surveyors of quality assessment 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, assessors, surveyors or officials, as the case may be, in relation to the conduct of the trial, or the functioning of YEC-1.

**6. Detailed instructions:**

**6.1. Receipt of notification of an Audit/Inspection and dissemination of information:**

6.1.1. On receipt of written/mailed communication regarding audit/inspection visit to YEC-1, the Member-Secretary will inform the Chairperson, YEC-1 members and the Head of Institution, if applicable about the date and purpose of the audit/inspection. The YEC-1 members will take note of the proposed date(s) of the audit/inspection/survey and make necessary arrangements to be present on the day of such audit/inspection/survey, if so required by the Chairperson/Member-Secretary.

**6.2. Preparing for the audit:**

6.2.1. The Chairperson will communicate the responsibility of preparation for the audit visit to the Member-Secretary or designated member(s) of YEC-1 with the assistance of the Secretarial staff.

6.2.2. The Member Secretary and/or designated YEC-1 member/s will make arrangements in accordance with the steps mentioned in the checklist. (Ann01/SOP 20/v3)

6.2.3. The Member-Secretary or other designated YEC-1 member will ensure that they comply with the prior requirements of the

auditor/assessor/surveyor such as uploading the relevant documents, providing access to the protocol database, and filling out necessary forms.

- 6.2.4. Care should be taken to ensure that all documents are made available for easy and quick access.
- 6.2.5. Member-Secretary or other designated YEC-1 member will take responsibility to ensure that the necessary audit/inspection/survey fees have been remitted and the receipts made available, upon request.

**6.3. On the day(s) of the visit/audit/inspection:**

- 6.3.1. The Chairperson/Member-Secretary/designated member(s) will be present throughout the audit
- 6.3.2. The Chairperson will welcome and accompany the auditors/inspectors to the reserved meeting room.
- 6.3.3. The auditors/inspectors state purpose of the visit and provide details of the type of information that is needed.
- 6.3.4. The Member-Secretary will take confidentiality agreement from the auditors/inspectors before providing any confidential details or before permitting the auditors/inspectors/surveyors to attend the YEC-1 meetings, as per SOP05/v3.
- 6.3.5. The Chairperson/Member-Secretary/YEC-1 members/ Secretarial staff will respond to the requirements of the audit by
  - 6.3.5.1. By attending the opening and closing meetings at the start and end of the audit/inspection/survey
  - 6.3.5.2. Answering questions asked by the auditors/inspectors clearly, responsibly and professionally
  - 6.3.5.3. Providing YEC-1 related and protocol-related documents, communications/letters, SOPs or any other document/file concerned with the YEC-1 as required for the

audit/inspection after entering in the access log as per SOP 18/v3.

6.3.5.4. Accompanying them to trial sites, archival room, or any other site concerned with YEC-1 activities, required for audit/inspection

6.3.5.5. Making note of the observations, comments and recommendations of the auditors/inspectors.

**6.4. Preparation of the response and corrections of deficiencies:**

6.4.1. The Member-Secretary/designated YEC-1 member(s) will review comments and recommendations of the auditor/inspector and prepare the response accordingly in a timely manner.

6.4.2. The Member-Secretary/designated YEC-1 member(s) will plan corrective measures in case deficiencies have been pointed out in the audit/inspection report

6.4.3. The Chairperson will approve the response and the plan of corrective measures

6.4.4. The Member-Secretary will send the response and plan of corrective measures to the auditor/inspector within the stipulated time

6.4.5. The Chairperson will implement corrective action and set a timeline for the same

6.4.6. The Chairperson will recommend to the YEC-1 necessary preventive measures in order to avoid such deficiencies in the future

6.4.7. Wherever necessary, the changes will be reflected in the SOPs so that they can be implemented in the future

6.4.8. The Chairperson may plan an internal follow-up audit in order to verify the changes implemented (if applicable).

6.4.9. The Member Secretary/designated YEC-1 member should report the outcome of the internal follow-up audit to the Chairperson



**6.5. Recording the audit/inspection:**

- 6.5.1. The Member-Secretary/designated YEC-1 member/Secretarial staff must maintain a record of the audit/inspection visit reports and action plans in a separate audit/inspection file.
- 6.5.2. The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

**7. Annexures**

- 7.1. Ann01/SOP20/v3: Checklist for the preparation for Audit and Inspection of YEC-1

**Ann01/SOP20/v3:  
Checklist for the preparation for Audit and Inspection of YEC-1**

<b>Sl.No</b>	<b>Checklist item</b>	<b>Check if completed (with date)</b>
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 YEC-1 members and staff have been informed about the date(s) and time	
4	Chairperson designates Member-Secretary/YEC-1 member as coordinator	
5	Ensure availability of YEC-1 related information: mandate, terms of reference, organization chart (in the print form) in the YEC-1 Secretariat	
6	Ensure availability of latest copy/copies of signed SOPs in print form in the office and/or in electronic form on the YEC-1 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 YEC-1 Secretariat	
9	<p>Check files of ongoing and complete research studies for the presence of all signed documents as stated below and to note any missing/incomplete documents and actions taken:</p> <ul style="list-style-type: none"><li>A. Records regarding applications of research studies for review including protocols and related documents</li><li>B. Protocol Assessment Records – Comments of YEC-1 members, meeting, agenda, minutes (documented in individual study file or separately in meeting records file)</li><li>C. Communication records with investigator (documented in individual study file)</li><li>D. Amendment Approvals (documented in individual study file)</li><li>E. SAE reports and SAE related communications with investigator and regulators</li><li>F. Protocol deviation/violation/exception reports (documented in individual study file)</li><li>G. Continuing and final completion/termination reports (documented in individual study file)</li></ul>	
10	Ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of YEC-1 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 labeling and index of study files and storage cabinets	
15	Decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare an action plan and conduct follow-up audit (if applicable)	
16	Report findings and report received regarding	



	audit/inspection to YEC-1 members at the subsequent YEC-1 meeting	
17	Make 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	

## 8. Flow Chart

