Title: Preparing for Audit of Yenepoya Ethics Committee- 1

SOP Code: SOP20/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date 1/6/2023

Reviewed by:

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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date 6/6/23

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date 7/6/23

Details of superseded SOP20

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOPv4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Glossary section added in the SOP 2. Internal audit added new

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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/inspection of the YEC-1 that may be conducted by an authorized agency internal to Yenepoya deemed to be University or any authorized external agency like regulatory authorities, accreditation bodies, recognition bodies, etc.

3. **Definitions:**

3.1. **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.

3.2. **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. **Responsibility:**

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

4.1.1. Designate the Member-Secretary (as coordinator) and/or one or more YEC-1 members to take responsibility of preparing for the audit/inspection

4.1.2. Encourage all the YEC-1 members to take part in the audit/inspection responsibly and professionally

4.1.3. Welcome the auditing/inspecting team and facilitate smooth conduct of the audit/inspection

4.1.4. Ensure timely preparation of the YEC-1 response to the audit/inspection report and approve the same

4.1.5. Approve the corrective action in response to any deficiencies found and as per the recommendation in the audit/inspection report

4.1.6. Plan an internal follow-up audit in order to verify the changes implemented (if applicable).

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

4.2.1. Receive the details of audit/inspection from the auditors/inspectors and acknowledge

4.2.2. Communicate the details of the proposed audit/inspection to the Chairperson, YEC-1 members and the University

4.2.3. Communicate and coordinate with the concerned persons, and make logistic arrangements for the visit of the auditors/inspectors

4.2.4. Study the requirement for the audit/inspection and prepare accordingly

4.2.5. Keep the documents and office ready for the audit/inspection

4.2.6. Inform the concerned principal investigators and the concerned hospital authorities to keep the trial sites ready, if site visit by the auditors/inspectors is expected or scheduled

4.2.7. Prepare and submit the response of the YEC-1 to the audit/inspection report in a timely manner

4.2.8. Prepare the corrective action report as per the deficiencies listed in the audit report.

4.3. **YEC-1 Member(s) will:**

4.3.1. Assist the Member-Secretary/Coordinator during the preparation for the audit, if so assigned by the Chairperson

4.3.2. Take the responsibility of preparation for the audit/ inspection if designated by the Chairperson

4.3.3. Be present at the time of audit/inspection

4.3.4. Take part in the interview and meeting with the audit/inspection team

4.4. **YEC-1 Secretariat will:**

4.4.1. Assist the Member-Secretary in keeping the documents ready for audit/inspection

4.4.2. Be available to answer questions and present the necessary documents during audit or inspection

4.4.3. Assist the Member-Secretary in preparing the corrective action report as required following the audit

4.5. **University authorized representative will:**

4.5.1. Make themselves available to attend the opening and closing (debriefing) meetings convened by the auditors/inspectors

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 Secretariat.

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/v4)

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. Member-Secretary or other designated YEC-1 member will take responsibility 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 the 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/v4.

6.3.5. The Chairperson/Member-Secretary/YEC-1 members/ Secretariat will respond to the requirements of the audit by

6.3.5.1. 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 protocols 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/v4.

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

6.5. Internal audit

6.5.1. The Chairperson may plan an internal follow-up audit in order to verify the changes implemented.

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

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

6.5.4. The audit will be conducted on a regular basis

6.6. Recording the audit/inspection:

6.6.1. The Member-Secretary/designated YEC-1 member/Secretariat will maintain a record of the audit/inspection visit reports and action plans in a separate audit/inspection file.

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

7. References:

Indian GCP Guidelines, 2001

8. Annexures:

8.1. Ann01/SOP20/v4: Checklist for the preparation for Audit and Inspection of YEC-1

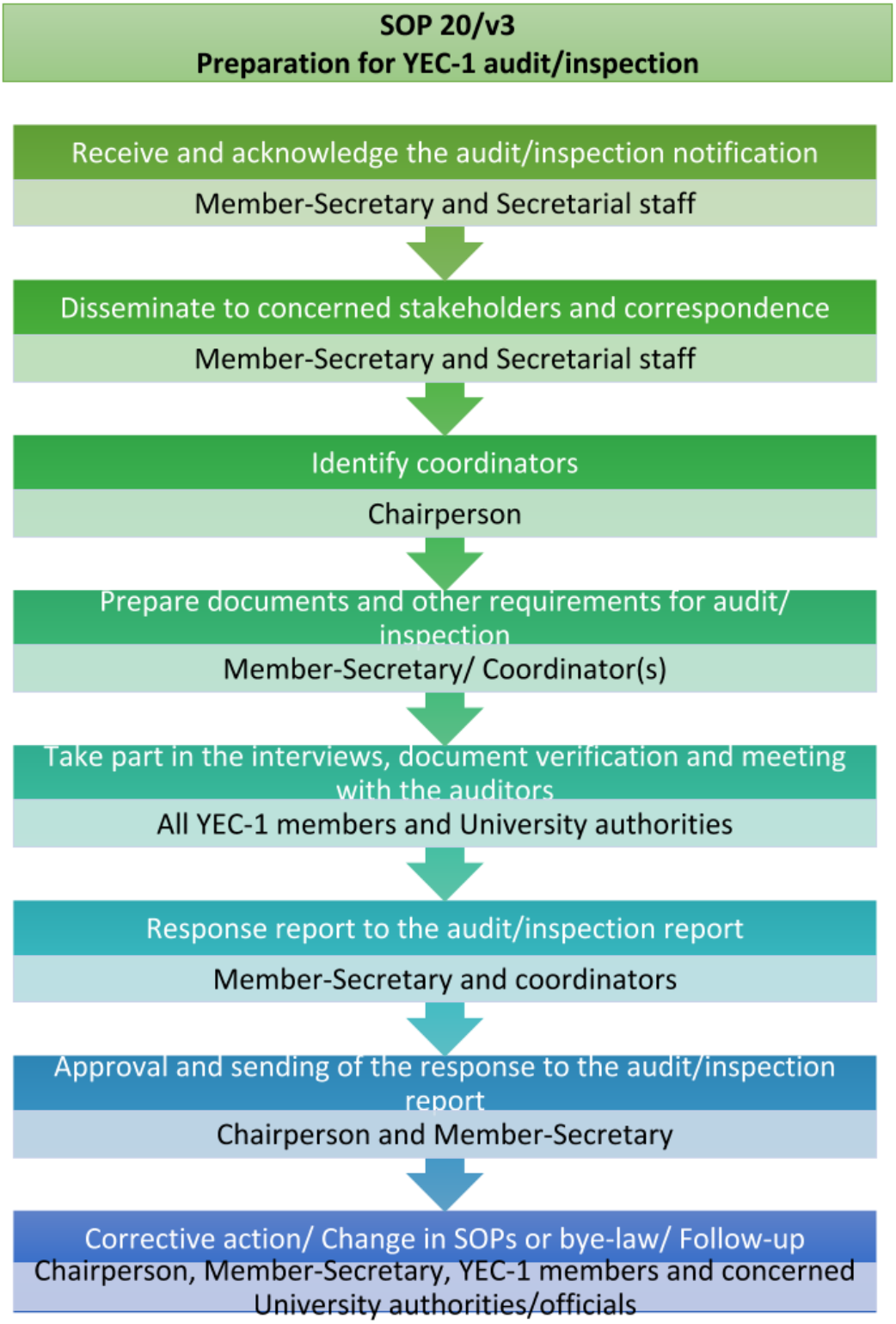
Ann01/SOP20/v4

Checklist for the preparation for Audit and Inspection of YEC-1

Sl. No	Checklist item	Check if complete (with date)
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 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 documents and actions taken: A. Records regarding applications of research studies for review including protocols and related documents B. Protocol Assessment Records – Comments of YEC-1 members, meeting, agenda, minutes (documented in individual study file or separately in meeting records file) C. Communication records with investigator (documented in individual study file) D. Amendment Approvals (documented in individual study file) E. SAE reports and SAE related communications with investigator and regulators F. Protocol deviation/violation/exception reports(documented in individual study file) G. Continuing and final completion/termination reports (documented in individual study file)	
10	Ensure availability of documents regarding list of YEC-1 members, tenure, appointment details, CVs, baseline and periodic training of YEC-1 members	
11	Ensure availability of documents regarding appointment, CVs and training of secretariat staff	
12	Ensure measures for maintaining security of electronic database and office records	
13	Ensure maintenance, retrieval, storage, archival and tracking of study files 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 the findings 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	

9. **Flow Chart:**


SOP 20/v3
Preparation for YEC-1 audit/inspection
Receive and acknowledge the audit/inspection notification
Member-Secretary and Secretarial staff
Disseminate to concerned stakeholders and correspondence
Member-Secretary and Secretarial staff
Identify coordinators
Chairperson
Prepare documents and other requirements for audit/ inspection
Member-Secretary/ Coordinator(s)
Take part in the interviews, document verification and meeting with the auditors
All YEC-1 members and University authorities
Response report to the audit/inspection report
Member-Secretary and coordinators
Approval and sending of the response to the audit/inspection report
Chairperson and Member-Secretary
Corrective action/ Change in SOPs or bye-law/ Follow-up
Chairperson, Member-Secretary, YEC-1 members and concerned University authorities/officials

10. **Glossary:**

CDSCO: Central Drugs Standard and Control Organisation

DCGI: Drugs Controller General of India

GCP: Good Clinical Practice

ICF: Informed Consent Form

ICMR: Indian Council of Medical Research

PIS: Participant Information Sheet

Protocol: Protocol refers to a set of documents that contain the detailed components of the proposed study

Protocol Amendment: Any change in any of the protocol components (title, study design, methodology, sample size, sample/data collection, sample/data handling, data analysis or any other change) after YEC-1 approval is referred to as protocol amendment

Protocol Deviation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in increased risk to participants

Protocol Violation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in increased risk to participants

SAE: Serious Adverse Event