Title: Site Monitoring Visit and Audit of Protocols

SOP Code: SOP16/v4

Effective Date: 01/07/2023

Prepared by:

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

Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP subcommittee	Signature with Date 1/6/23

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Details of superseded SOP16

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 SOP16/v4

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. Typographical errors corrected 3. Added plan for maintaining roster for SMV-related communications 4. Add a section on auditing of protocols along with the checklist

Table of Contents:

1. **Purpose:** The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring visit (SMV) and auditing of the protocols approved by Yenepoya Ethics Committee-1 (YEC-1).

2. **Scope:** This SOP applies to all protocols approved by YEC-1 for which a routine or for-cause on-site monitoring/auditing should be undertaken.

3. **Definitions:**

   3.1. **Site monitoring**: Site monitoring is a post-approval activity of YEC-1 in which the site monitoring subcommittee will visit the research site, inspect the site for availability of requirements as per the approved protocol, verify documents to confirm protocol adherence and interview participants or observe recruitment/informed consent process, if possible.

      3.1.1. **For cause SMV:** When the site monitoring is conducted for a specific reason(s) (listed below) as determined during the research period.

      3.1.2. **Routine SMV:** When the site monitoring is planned at the time of approval of the protocol based on the risk assessment and will include regulated clinical trials, clinical studies involving vulnerable populations, and other interventional studies posing more than minimal risk to the participants.

   3.2. **Audit of the protocol files:** Audit is a post-approval activity in which YEC-1 members conduct an audit of protocol files to confirm protocol adherence and identify PD/PVs in the data collection/ICF in a given protocol. Audit is conducted for studies which need oversight but do not warrant a visit to the site as in SMV.

4. **Responsibilities:**

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

      4.1.1. Approve the formation of a SMA/audit subcommittee and its members

      4.1.2. Oversee and approve all SMVs/audits reports (scheduled and unscheduled)

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

      4.2.1. Ensure that the resolution to determine the periodicity of SMV/audit for a protocol, is done in the YEC-1 meeting, at the time of approval.

      4.2.2. Ensure that the decision on the periodicity of SMVs/audit is recorded in the minutes (as resolution), in the decision form and in the roster.

      4.2.3. Constitute a site monitoring/audit subcommittee and its constituent members

      4.2.4. Ensure communications are sent on time, to all concerned stakeholders.

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

      4.3.1. Maintain the SMV and audit roster and update it regularly from time to time.

      4.3.2. Remind the Member-Secretary of upcoming scheduled SMVs and audits

      4.3.3. Prepare the communications and necessary files required for SMV and audits

4.3.4. Send reminders to all the members on the day of the SMV and audit

4.3.5. Coordinate with the onsite representative of the PI and the SMV subcommittee members for the smooth conduct of the SMV

4.3.6. Coordinate with the PI and audit subcommittee members for the smooth conduct of the audit

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

4.4.1. Cooperate with the Chairperson/Member-Secretary/Secretariat in the smooth conduct of the SMV and audit

4.4.2. Actively take part in the SMV and audits

4.4.3. Compile the SMV/audit report on time, and submit it to YEC-1 Secretariat.

4.4.4. Assist the Member-Secretary in assessing the audit reports submitted by the PIs, in a timely manner, as recommended by YEC-1.

5. **Mandate:**

5.1. Indian Council of Medical Research (ICMR): "It is recommended that ECs should follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance or improve the function."[1]

5.2. Indian GCP Guidelines: "The Ethics Committees are entrusted not only with the initial view of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programmes till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research."[2]

6. **Detailed instructions:**

6.1. **Decision for "routine" site monitoring:**

6.1.1. For all full review protocols, the decision of routine SMV and its frequency will be made depending on the level of risk to the participants at the time of approval in YEC-1 meeting

6.1.2. The SMV schedule for the protocol will be recorded in the resolution, decision form and in the SMV roster

6.1.3. YEC-1 may conduct SMV for clinical trials, studies with high risk or in studies involving vulnerable populations

6.1.4. YEC-1 may conduct SMV at the time of first recruitment or any time when the study is ongoing depending on YEC-1 decision.

6.2. **Decision for "for-cause" SMV:** For-cause-SMV may be decided in the following circumstances:

[1] ICMR's National Ethical Guidelines for Biomedical Research involving Human Participants 2017 (4.12.1).
[2] Indian GCP Guidelines (2.4.2) http://www.cdsco.nic.in/html/GCP1.html accessed on 13 August 2019 at 1145 hours

6.2.1. To observe the PI or a designated research team member carry out the IC process in a regulatory clinical trial based on the periodic review reports

6.2.2. When high number of or frequent PD/PVs are noticed

6.2.3. Large number of studies carried out at the study site or by a single investigator

6.2.4. Large number of Serious Adverse Events (SAE) reports

6.2.5. High participant recruitment rate

6.2.6. Failure to submit the required documents despite repeated requests

6.2.7. Non-compliance of the PI to standards of care in research as based on the Indian GCP guidelines.

6.2.8. Complaints about the research trial from a participant or any other stakeholder.

6.2.9. Any adverse media report regarding a research proposal approved by YEC-1

6.2.10. Adverse information regarding a research proposal approved by YEC-1 - received from any other source

6.2.11. Non-compliance with EC directions/current regulations

6.2.12. Misconduct by an investigator of a research proposal approved by YEC-1

6.2.13. Any other cause as decided by YEC-1

6.3. **Maintenance of roster for SMV/Audit**

6.3.1. The Secretariat will maintain a roster of the SMV/Audit schedule in an Excel sheet (Ann05/SOP16/v4)

6.3.2. The excel sheet will be updated after every YEC-1 meeting during which the schedule for the full review protocols is made if the protocol is approved and the expedited review protocol approvals are ratified

6.3.3. The Secretariat will add any for-cause SMV visits in the roster as and when they are scheduled

6.3.4. The Secretariat will identify the protocols for SMV/audit at the beginning of the month and initiate the preparation for the same.

6.4. **Preparation for SMV**

6.4.1. Member-Secretary will identify one or more YEC-1 members to constitute the site monitoring subcommittee after approval of the Chairperson

6.4.2. If an SAE has been reported at the site, the lay person will also be included in the SMV subcommittee to monitor the compensation issues.

6.4.3. SMV subcommittee members will be emailed about the SMV schedule.

6.4.4. The tentative date and agenda of SMV will be decided by the subcommittee and communicated to the PI - at least 2 calendar days prior to the visit date - with a request to be available at the site, at the date and time agreed upon.

6.4.5. If the PI is unable to be present for the SMV, then they will designate another responsible member of the research team to be present on that time and date.

6.5. **During the SMV**:

6.5.1. The SMV subcommittee will review the relevant protocol documents and reference material (if required) in the YEC-1 office, be updated about the study and make appropriate notes before visiting the site.

6.5.2. Members will take with them, SMV report form (Ann01/SOP16/v4 and Ann02/SOP16/v4) and protocol file, after entering in the document access log.

6.5.3. The members will meet with the Principal Investigator upon reaching the site and begin the process of site monitoring.

6.5.4. In case the study site is deserted or closed and PI or other designated person is unavailable and not contactable, the subcommittee shall wait for a period of 15 min before returning, and file a report stating "Unavailable for monitoring"

6.5.5. Suitable immediate action may be recommended by the SMV subcommittee.

6.5.6. The Member-Secretary will obtain approval from the Chairperson and communicate this to the PI, and then ratify this decision in the next meeting in this regard and the same will be minuted and conveyed to the PI.

6.5.7. The following will be checked as per the checklist:

6.5.7.1. Adherence to the log of delegation of responsibilities of study team

6.5.7.2. Adherence to the latest, approved version of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.

6.5.7.3. Appropriateness and completeness of the informed consent process, if possible, by observation

6.5.7.4. Completeness and correctness of the IC forms with respect to the correct version, correct language and signatures and timing.

6.5.7.5. Completeness of randomly-selected participant files as per standards laid down in Indian GCP guidelines

6.5.7.6. Appropriateness of the management of IP, accountability and documentation throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study), access log, storage time, conditions, expiry dates, and sufficient supplies available (wherever applicable)

6.5.7.7. Appropriateness of management of human body samples collected for research (collection, labeling, coding, disposal, storage, log)

6.5.7.8. Whether the investigator is following the approved version of the protocol and all approved amendment(s), if any

6.5.7.9. That the investigator and the investigator's trial staff are adequately

informed about the trial, and appropriately trained.

6.5.7.10. Research team functioning according to delegation log form of the approved protocol.

6.5.7.11. Enrollment of subjects is as per the inclusion and exclusion criteria.

6.5.7.12. Whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. adverse events (AEs) and SAEs for the volume or severity of adverse events.

6.5.7.13. The lay person will check whether the compensation issues have been adequately and appropriately addressed

6.5.7.14. Ensure that documentation is filed appropriately

6.5.7.15. Source documents for their completeness

6.5.7.16. The views of the participants (if possible) and charter of participant rights & responsibilities is prominently displayed

6.5.7.17. Security issues of the trial room, data, archival, restriction of access, maintenance of logs, etc

6.5.8. The member(s) will fill the SMV report form (Ann01/SOP16/v4) and informed consent observation form (Ann02/SOP16/v4 if applicable), sign and date it and submit it to the YEC-1 office.

6.6. **Preparation of the report:**

6.6.1. The subcommittee will compile and submit the completed report form (Ann01/SOP16/v4) and IC observation from (Ann02/SOP 16/v4 - if applicable) to YEC-1 Secretariat within 7 calendar days of conducting a SMV or at the time of immediate next meeting of YEC-1 (whichever is earlier).

6.6.2. The report should describe the findings of the monitoring visit in an objective manner specifying protocol adherence and protocol deviations/violations.

6.7. **Decision making on an urgent ground:**

6.7.1. If the subcommittee has findings that directly or indirectly impact the safety of participants, they will inform the Member-Secretary immediately.

6.7.2. The Member Secretary will take up the matter with the Chairperson, and call for an extraordinary meeting within calendar 2 days.

6.7.3. In the extraordinary meeting, after assessing the seriousness of the impact on the safety of participants, the research may be terminated, or suspended or allowed to continue with appropriate amendments, or allowed to continue with a reprimand.

6.7.4. The final decision taken by the Chairperson, will be informed at the next YEC-1 meeting and will be recorded in the SMV report form

(Ann01/SOP16/v4) and in the minutes.

6.8. **Audit of the files:**

6.8.1. YEC-1 will conduct audits of ongoing studies to check for protocol adherence and detection of any unreported protocol deviations or adverse events

6.8.2. Protocols selected for audit will include protocols which need post-approval oversight but do not warrant SMV

6.8.3. YEC-1 will send an intimation to the PI to report to YEC-1 office on the specified data and time with all the study-related documents including the signed informed consent documents, filled data collection forms, the master sheet of the data and any other documents related to the study.

6.8.4. A subcommittee consisting of two or more members of YEC-1 identified for the conduct of audit, will scrutinize the documents to affirm protocol adherence as per the checklist provided.

6.8.5. Based on the observation, action is initiated if protocol deviations or violations or non-compliances are detected as per SOP 11/v4

6.8.6. The report of the audit is placed in the YEC-1 meeting for discussion and ratification of the decision.

6.9. **Decision in YEC-1 meeting:**

6.9.1. The Member-Secretary will present the SMV/audit report at the subsequent YEC-1 meeting

6.9.2. The subcommittee members will provide additional inputs, so as to enable a proper assessment of the report.

6.9.3. YEC-1 will deliberate on the issues and take appropriate specific action or combination of actions, by voting, some of which are listed in the next point

6.10. **Final decision:**

6.10.1. No further action required

6.10.2. Request information

6.10.3. Recommend further action:

6.10.3.1. Restrict further enrollment of participants

6.10.3.2. Recommend additional training of the PI or trial staff

6.10.3.3. Recruit additional trained members in the study team

6.10.3.4. Cause the PI to amend the protocol such that the risks are mitigated.

6.10.3.5. Temporary suspension of study until further decision at YEC-1

6.10.3.6. Submit PD/SAE/periodic review form or any other as needed

6.10.3.7. Termination of the study

6.11. **Communication of the final decision:**

6.11.1. The Secretariat will convey the decision of YEC-1 to the Principal Investigator in writing within 7 calendar days of the meeting

6.11.2. A copy of the report will be kept in the protocol file

7. **References:**

7.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

7.2. New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Act, 1940

7.3. Indian GCP Guidelines, 2001

7.4. SOP7A/v4: Initial Full-Board Review of Research Study Protocol

8. **Annexures:**

8.1. Ann01/SOP16/v4: Site Monitoring Visit Report

8.2. Ann02/SOP16/v4: Monitoring of informed consent process

8.3. Ann03/SOP16/v4: Monitoring of Audiovisual recording of consent Process

8.4. Ann04/SOP16/v4: Checklist for audit

8.5. Ann05/SOP16/v4: Roster for SMV/Audit (Template)

Ann01/SOP16/v4

Site Monitoring Visit Report

1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study	Clinical trial/ academic clinical trial/ observational study Vulnerable population involved: Yes/No
6	Date of YEC-1 approval:	
7	YEC-1 approval valid until	
8	Date of first recruitment	
9	Date of last recruitment	
10	Type of SMV	Routine/ For cause
11	Study status	Study status: Active/suspended/terminated
12	Recruitment status	Recruitment: Ongoing/complete

13	Investigational product, accountability and documentation throughout the product flow at the study site (Arrival, dispensing, use, return from the subject, return/destruction after the study, labeling, access log, storage time, storage conditions, expiry dates, sufficient supplies available	Appropriate/ Not appropriate Comments:
14	Human body samples collected for research: Collection, labeling, coding, disposal, storage, log, wherever applicable)	Appropriate/ Not appropriate Comments:
15	Participant recruitment details	Sample size approved:
		Screened:
		Recruited:
		Withdrawn:
		Discontinued:
		Completed:
		Ongoing:
16	PI/Team member present for the SMV	Yes/No Comment
17	Site facilities are appropriate	Yes/No Comment
18	Approved version of ICD followed	Yes/No Comment
19	Consent has been taken in their native language?	Yes/No Comment
20	Any other observations about the ICDs?	Yes/No Comment
21	Approved version of the protocol followed	Yes/No Comment
22	Approved version of the case record from followed	Yes/No Complete: Yes/No Comment:
23	Inclusion and exclusion criteria have been adhered to	Yes/No Comment
24	Fair/equitable distribution of participants	Yes/No Comment
25	Adverse events found	Yes/No Comment
26	SAEs found	Yes/No Comment
27	SAE reporting done as per specified timelines	Yes/No Comment Provide details if yes

28	Compensation paid in case of SAE	Yes/No Comment Provide details if yes
29	Protocol deviations observed	Yes/No Reported to YEC-1: Yes/No Comment Provide details if yes
30	Appropriate security of trial site, data and IP maintained	Yes/No Comment
31	Informed consent process observed	Yes/No If yes: fill Ann 02/SOP16v4
32	Participant safety and wellbeing assured	Yes/No Comment
33	Any other observations:	
	Details of the SMV visit	
1	Date	
2	Time (From and to)	Start time: End time
3	Provisional decision:	1. No further action required 2. Request information 3. Recommend further action
4	Names of the SMV members with signature and date	
5	Extract of resolution of minutes YEC-1 meeting NO: Date of the meeting	
6	Final decision	1. No further action required 2. Request information 3. Recommend further action
	Signature of Chairperson with date:	

Ann02/SOP16/v4

Observation of informed consent process

1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study	Clinical trial/ academic clinical trial/ observational study Vulnerable population involved: Yes/No
6	Date of YEC-1 approval:	

7	YEC-1 approval valid until	
8	Date of first recruitment	
9	The informed consent process was taken by the research team member designated to take the informed consent	Yes/No Comments
10	The informed consent was carried out in the room with privacy	Yes/No Comments
11	Informed consent document was the same version as approved by YEC-1	Yes/No Comments
12	The informed consent was obtained in the regional language that the participant is conversant with	Yes/No Comments
13	The participant was made to feel at ease and no coercion was applied by the PI or the research team	Yes/No Comments
14	Adequate privacy was provided	Yes/No Comments
15	PI's demeanor was open and friendly, inviting participant to ask questions	Yes/No Comments
16	The PI reconfirmed whether the participant had understood the nuances of the research and that this was different from therapy	Yes/No Comments
17	PI described (in simple language) the choice to enroll or not; right to refuse; possible alternative; risks and benefits	Yes/No Comments
18	The PI made it clear about reimbursement for time spent; compensation in the event of adverse event; and the role of nominee in case of SAE (including death)	Yes/No Comments
19	PI provided a copy of the participant information sheet to the participant and encouraged him/her to read it	Yes/No Comments
20	The PI gave ample time to the participant to consider the risks and benefits before signing IC document	Yes/No Comments
21	PI gave one copy of the informed consent form to the participant to keep	Yes/No Comments
22	In the case of a minor, parent/LAR was present and included in the discussion	Yes/No Comments
23	In case of a minor (between 12 and 18 years) assent form was explained and signature of the participant taken	Yes/No Comments
24	The overall time taken for the PI to complete the	Yes/No

	IC process (in minutes)	Comments
	Details of the informed consent observation	
1	Date	
2	Time (From and to)	Start time: End time
3	Provisional decision:	1. No further action required 2. Request information 3. Recommend further action
4	Names of the YEC-1 members who observed the informed consent with signature and date	
5	Extract of resolution of minutes YEC-1 meeting No: Date of the meeting	
6	Final decision	1. No further action required 2. Request information 3. Recommend further action
	Signature of Chairperson with date:	

Ann03/SOP16/v4

Monitoring of Audiovisual recording of Informed Consent Process

1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study	Clinical trial
6	Date of YEC-1 approval:	
7	YEC-1 approval valid until	
8	Date of first recruitment	
9	Facility where the IC process should be carried out is well lit, noise-free, private?	
10	Is the IC process and form in a language the participant/LAR understands best and is literate in?	
11	Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during IC process was done?	

12	Was information provided to the participant/ LAR/ witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules?	
13	Was information provided to the participant/ LAR/ witness (as applicable) that the confidentiality of information and privacy of participants is assured?	
14	Was information provided to the participant/ LAR/ witness that the recording may be shown to government agencies or members from YEC-1?	
15	Was explanation or narration provided by the person conducting the informed consent discussion?	
16	Were the questions asked by the potential participant/LAR answered satisfactorily?	
17	Did the PI allow ample time and opportunity to read/understand the information in the IC document or discuss the same with family members?	
18	Did the PI or a member of the study team encourage reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in IC and stating whether participant agrees or not for each statement?	
19	Was there appropriate documentation of signatures of all those involved in the IC process?	
20	Was there adequate clarity and completeness of the AV recording of the informed consent process?	
21	Was the recording stored in a password protected laptop/desktop computer and/or hard drive and/or labeled CD with access allowed only to the PI and designated members of the study team?	
	Details of the monitoring of the AV recording of the informed consent	
1	Date	
2	Time (From and to)	Start time: End time
3	Provisional decision:	1. No further action required 2. Request information 3. Recommend further action
4	Names of the YEC-1 members who observed the informed consent with signature and date	
5	Extract of resolution of minutes YEC-1 meeting No: Date of the meeting	

6	Final decision	1. No further action required 2. Request information 3. Recommend further action
	Signature of Chairperson with date:	

Ann04/SOP16/v4:

Checklist for audit

1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study	Clinical trial/ academic clinical trial/ observational study Vulnerable population involved: Yes/No
6	Date of YEC-1 approval:	
7	YEC-1 approval valid until	
8	Date of first recruitment	
9	Whether sample size is restricted to the sample size approved?	Yes/No Comments
10	Whether the sample size is collected within the validity period of EC clearance? (and not before or after)	Yes/No Comments
11	Whether the approved version of the protocol is followed?	Yes/No Comments
12	Whether the approved version of the data collection form is followed?	Yes/No Comments

13	Whether the approved version of the informed consent form is followed?	Yes/No Comments
14	Whether the informed consent forms are signed by both: the PI and the participant?	Yes/No Comments
15	Whether any participants have withdrawn after giving informed consent? (Specially look for this in follow-up studies)	Yes/No Comments
16	Whether any participants have been discontinued by the PI after taking informed consent?	Yes/No Comments
17	Any adverse events noted?	Yes/No Comments
18	Any other observation:	Yes/No Comments
	Details of the monitoring of the AV recording of the informed consent	
1.	Date	
2.	Time (From and to)	Start time: End time
3.	Provisional decision:	1. No further action required 2. Request information 3. Recommend further action
4.	Names of the YEC-1 members who observed the informed consent with signature and date	

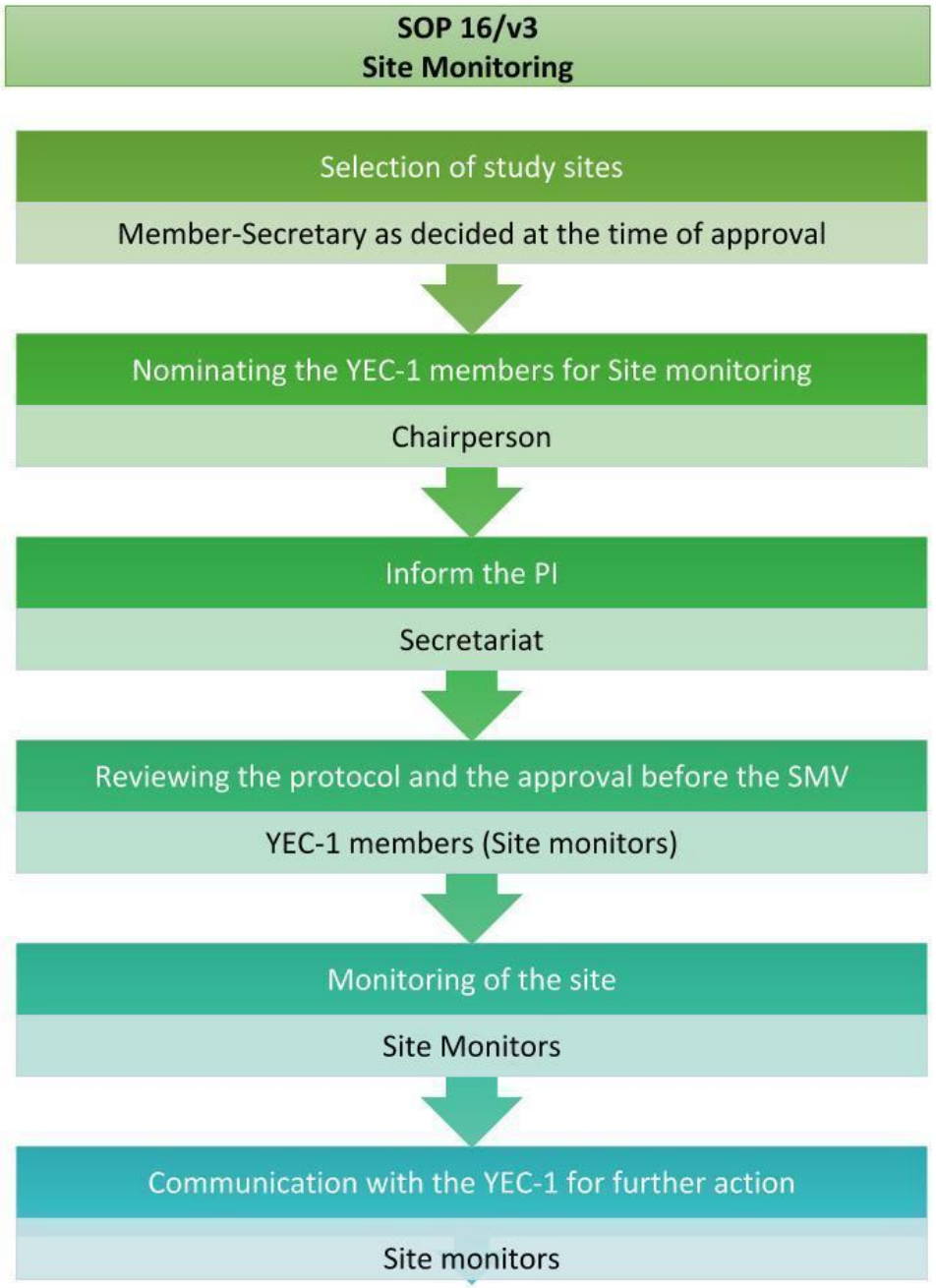
5.	Extract of resolution of minutes YEC-1 meeting No: Date of the meeting	
6.	Final decision	1. No further action required 2. Request information 3. Recommend further action
	Signature of Chairperson with date:	

Ann05/SOP16/v4: Roster for site monitoring visits

(to be maintained in the excel sheet and updated after every YEC-1 meeting)

Protocol No.	Title	Name of PI	Date of EC sanction	EC validity	SMV or audit recommended	Schedule for SMV/Audit	Add column for each month of the year	Date when SMV/Audit conducted

9. Flowchart:


SOP 16/v3
Site Monitoring
Selection of study sites
Member-Secretary as decided at the time of approval
Nominating the YEC-1 members for Site monitoring
Chairperson
Inform the PI
Secretariat
Reviewing the protocol and the approval before the SMV
YEC-1 members (Site monitors)
Monitoring of the site
Site Monitors
Communication with the YEC-1 for further action
Site monitors

10. Glossary:

ADE: Adverse Drug Event

ADR: Adverse Drug Reaction

CDSCO: Central Drugs Standard and Control Organisation

DCGI: Drugs Controller General of India

DSMB: Data Safety Monitoring Board

GCP: Good Clinical Practice

ICD: Informed Consent Document

ICF: Informed Consent Form

ICH-GCP: International Committee for Harmonization - Good Clinical Practice

ICMR: Indian Council of Medical Research

IP: Investigational product: Drug (or device, instrument) that is being tested in a clinical trial

LAR: Legally acceptable representative

PI: Principal Investigator

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 (PD): 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 (PV): 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

SMV: Site Monitoring