YENEPOYA
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Title: Site Monitoring and Post- Monitoring Activities

SOP Code: YEC2/SOP16/v2

Effective Date: 24.02.2024

Prepared by:

Dr. K. Leena Pramod Convenor, YEC2 SOP Subcommittee	Signature with date 24/02/2024

Reviewed by:

Dr. Sridevi K Member, YEC2 SOP Subcommittee	Signature with Date 24/02/2024

Approved by:

Dr. Animesh Jain Chairperson , YEC2	Signature with Date 24/02/24

Notified by:

Registrar, Yenepoya(Deemed to be university)	Signature with Date Registrar YENEPOYA (Deemed to be University) 24/02/24

Details of superseded SOP16/v1

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP16/v2

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. K .Leena Pramod	v2		1. Definition added in the SOP 2.Responsibility added in the SOP 3.Added Reference to other applicable SOP's 4. Revised Flowchart

Table of Contents:

1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of a Yenepoya Ethics Committees 2(YEC 2) approved protocol.

2. Scope

This SOP applies to all YEC 2 approved studies for which a routine or for-cause on-site monitoring may be undertaken by the YEC 2.

3. Definitions

3.1. **Site monitoring**: Site monitoring(SM) is a post-approval activity of YEC- 2 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. **Routine monitoring**: 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.

3.1.2. **Remote Monitoring**: when the review study data is available with EC or when the study documents are shared via email, the type of monitoring is based on risks involved.

3.1.3. **For cause Monitoring**: EC chairperson & member secretary shall decide on studies applicable for “For Cause” monitoring based on criteria (listed below)

3.2. **Post monitoring (PM) of the protocol files**: In this post-approval activity YEC-2 members conduct an audit of protocol files to confirm protocol adherence and identify Protocol Deviation/Protocol Violations 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 Site monitoring

4. Responsibility

It is the responsibility of the Ethics Committee or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated YEC 2 member(s) to perform on-site monitoring of selected study site(s).

4.1. **YEC-2 Chairperson will**:

4.1.1. Approve the formation of a Site monitoring(SM) /post monitoring subcommittee and its members

4.1.2. Oversee and approve all SM /PM reports (scheduled and unscheduled)

4.2. **YEC-2 Member-Secretary will**:

4.2.1. Ensure that the resolution to determine the periodicity of SM/PM for a protocol, is done in the YEC-2 meeting, at the time of approval.

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

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

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

4.3. YEC-2 Secretariat will:

4.3.1. Maintain the SM /PM roster and update it regularly from time to time.

4.3.2. Remind the Member-Secretary of upcoming scheduled SM /PM

4.3.3. Prepare the communications and necessary files required for SM /PM

4.3.4. Send reminders to all the members on the day of the SM /PM

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

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

5. Mandate:

5.1 Indian Council of Medical Research (ICMR 2017):

"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]

5.3 New drugs Clinical trial Rules (2019)[3]:

"Ethics Committee should make, at appropriate intervals, an ongoing review of the trials for which they have reviewed the protocol. Such a review may be based on periodic study progress reports furnished by the investigator or monitoring and internal audit reports furnished by the sponsor or visiting the study sites"

ICMR's National Ethical Guidelines for Biomedical Research involving Human Participants 2017 (4.12.1)[1]

Indian GCP Guidelines (2.4.2) http://www.cdsco.nic.in/html/GCP1.html accessed on 12 July 2024 at 1145 hours[2]

NDCTR (2019)[3] – The Gazette of India : Extraordinary Part II – SEC.3 (I) - Third Schedule Pg 211

6. Detailed instructions:

6.1. Routine Monitoring

6.1.1For all full review protocols, the decision of routine SM and its frequency will be made depending on the level of risk to the participants at the time of approval in YEC-2 meeting

6.1.2 This should be recorded in the YEC 2 decision form (Ann03/SOP7A/v2) and in the YEC 2 minutes and SM roster.

6.1.3 *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the YEC 2, after approval by the Chairperson[1].

6.2 The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:

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 High number of protocol violations, or frequent violations or violations that significantly and unjustifiably increase the risk burden on the research participants.

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

6.2.3 Large number of Serious Adverse Events (SAE) reports

6.2.4High recruitment rate

6.2.5 Frequent failure to submit the required documents

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

6.2.7 Receipt of complaints about the research trial from any stakeholder[2].

6.2.8 Any adverse media report regarding a research proposal approved by YEC-2

6.2.9 Adverse information regarding a research proposal approved by YEC-2 received from any other source

6.2.10 Non-compliance with EC directions/current regulations

6.2.11 Misconduct by an investigator of a research proposal approved by YEC-2

6.2.12 Any other cause as decided by YEC- 2

6.3 Before the visit

6.3.1 Irrespective of the cause for conducting monitoring the following procedure will be followed.

6.3.2 The Member secretary will identify and select one or more YEC 2 members (henceforth referred to as monitor/s) to conduct monitoring of a site. Approval

will be taken from the chairperson. The selected members will be given an appointment letter in this regard from the secretariat.

6.3.3 The tentative date and agenda of monitoring will be decided by the monitors in consultation with the Member Secretary and Chairperson.

6.3.4 The final date will be communicated to the PI (with a request to be available) and monitors by the YEC 2 Secretariat.

6.3.5 The monitor will receive from the YEC 2 Secretariat and review the relevant project documents and reference material (if requested) and make appropriate notes.

6.3.6 Monitors will carry with them the site monitoring visit report form (YEC2/ Ann01/SOP 16/v1 and YEC2/ Ann02/SOP 16/v1) collected from the Secretariat (if applicable).

6.4 During the visit

6.4.1 Upon arrival at the study site, the monitor shall meet with the Principal Investigator and begin the process of site monitoring.

6.4.2 In case the PI is unavailable then a designated person with appropriate authority will receive the monitor and comply with all the requirements.

6.4.3 In case the study site is deserted or closed and the PI or any other designated person is unavailable and not contactable, the monitor shall wait for a period of 10 minutes before returning and file the report stating “Unavailable for monitoring”.

6.4..4 Suitable action may be taken by the YEC 2 in its next meeting in this regard and the same will be minuted and conveyed to the PI.

6.4.5 During site monitoring the monitor will follow the checklist (YEC2/ Ann01/SOP16/v1). The monitors will check:

- The log of delegation of responsibilities of study team
- Whether the site is using latest YEC 2 approved version of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
- The informed consent process, if possible, by observation

- Randomly-selected participant files to ensure that the documentation is as per standards laid down in Indian GCP guidelines and that the participants are signing the informed consent forms.
- Investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study)
- Storage times, conditions, expiry dates and sufficient supplies available (wherever applicable)
- Whether the investigator is following the approved protocol and all approved amendment(s), if any
- That the investigator and the investigator's trial staff are adequately informed about the trial
- Whether the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.
- That the investigator is enrolling only eligible subjects.
- Whether all serious adverse events (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.
- The project files of the study to ensure that documentation is filed appropriately
- The source documents for their completeness
- The views of the study participants, if possible

6.4.6 The site monitor will fill the site monitoring visit report form (YEC2/ Ann01/SOP16/**v2**) sign and date it.

6.5 After the visit

6.5.1 The Monitor will submit the completed site monitoring visit report form (*YEC2/ Ann01/SOP16/v1 and YEC2/ Ann02/SOP 16/v1 - if applicable*) to the YEC 2 secretariat within 7 working days of conducting a site monitoring visit or at the time of immediate next meeting of the YEC 2 (whichever is earlier).

6.5.2 The report should describe the findings of the monitoring visit without using judgmental words and in as objective a manner as possible.

6.5.3 The Member-Secretary will present the monitoring report at the next YEC 2 meeting and the concerned monitor will provide additional details/clarifications to members, as required.

6.5.4 YEC 2 will discuss the findings of the monitoring process and take appropriate specific action or combination of actions, by voting, some of which are listed below:

- Continuation of the project with or without changes
- Restrictions on enrollment
- Recommendations for additional training of the PI or trial staff
- Recruiting additional members in the study team
- Revising/providing qualifications/experience criteria for members of the study team
- Termination of the study, or suspension of the study, etc.

6.5.5 If the Monitor has findings that directly or indirectly, impact on safety of the participant, the monitor will inform the Member-Secretary on the same day. The Member Secretary will take up the matter with the Chairperson, post haste, and any one of the actions described above in 6.4.4 will be taken. The final decision taken by the Chairperson will be informed at the next YEC 2 meeting and will be recorded in the site monitoring visit report form (*YEC2/ Ann01/SOP16/v1*) and in the minutes.

6.5.6 The Secretariat will convey the decision of the YEC 2 to the Principal Investigator in writing within 14 working days of the meeting.

6.5.7 The Secretariat will place the copy of the report in the protocol file

7. Reference to other applicable SOPs:

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 YEC2/ SOP7A/v1: Initial Full-Board Review of Research Study Protocols

8. Annexures:

8.1. Ann01/SOP16/v1: Site Monitoring agenda
8.2. Ann02/SOP16/v2: Site Monitoring check list
8.3. Ann03/SOP16/v1: Site Monitoring Visit Report

8.3. Ann04/SOP16/v1: Template for memo
8.4. Ann05/SOP16/v1: Roster for Site monitoring (Template)
8.5. Ann06/SOP16/v1: Subcommittee for site monitoring
8.6. Ann07/SOP16/v1: Detailed flow chart of Site Monitor

8.1. Ann01/SOP16/v1: Site monitoring agenda

Study No.	
Study Title	
Name and Address of Site	
EC Monitoring visit date (s) DD-MMM-YYY (Followdate convention process as per institution/hospital)	
EC monitors Name (i.e. EC committee members (s) Name	
Scope of Visit	1) Site facility Visit i.e. screening, Consent room; Physical and medical examination room; sample collection, processing and storage room; investigational product

	storage room; other areas. 2) Meeting with Investigator and Site staff 3) Investigator Site Master File review 4) Audio-Video consent form review 5) Informed Consent Form review 6) Source document review 7) Investigational product accountability and handling 8) Study specific forms and log 9) Process of document management/handling at site 10) Site SOPs 11) Sample collection and processing activity 12) Sponsor and Regulatory communication 13) AE/SAE documentation (if any) 14) Protocol deviations (if any) 15) Othersi.e. Archival area please specify_____

	Prepared By: **(By EC monitor)**	**Approved By:** **(By EC member secretary)**	**Acknowledged by:** **(By site investigator)**
Name			
Role of person			
Signature & Date			

8.2. Ann02/SOP16/v2: Site Monitoring check list

Clinical trial monitoring checklist for review of clinical research studies

Study Number		**Name of Department**	
Study Title			
Name, address and contact details of site			
Date of study initiation		**Date of EC approval**	

Date of monitoring visit		
Opening meeting Conducted	Yes ☐ / No ☐	
	Members present during meeting are:	
	Name of EC monitors:	**Name of Site members:**

1. Type for monitoring :

a) Routine :- Yes/NO(Please tick mark suitable option**)**

b) For cause (state reason) – Yes/No(Please tick mark suitable option)
(If yes then select applicable below option)

i) High number of protocol violation/deviationii) Large number of SAE reporting

iii) Any significant non-compliance issues iv) High drop-out rate of study participant

v) Complaint from participants, any person vi) Vulnerable population

vii) Very low number of SAEs reported in comparison to other participating sites in a study.

viii) Large number of ongoing studies at the same timeframe by a particular investigator

x) Non-compliance to reporting requirements as per EC SOPs or Indian Clinical trial regulations/ guidelines

xi) Other (Specify):

b) Remote monitoring: Yes/No(Please tick mark suitable option)

2. LastEC monitoringdone,if any:	Yes ☐ Date of last visit: DD/MMM/YYYY	No ☐
3. Vulnerable population involved (Tick applicable box)	**1.** Pregnant women ☐ **2.** Children ☐	6. Illiterate ☐ 7. Handicapped ☐

	3. Elderly	☐	8. Economically & socially backward	☐
	4. Terminally ill	☐	9. Any Other	☐
	5. Fetus	☐		

4. Study Status(Tick applicable box):

1. Ongoing☐ 2. *Completed☐ 3.EnrollmentCompleted☐

4. Follow-up,extension study☐ 5. Suspended☐ 6. Terminated☐

Incaseof theresponse totheabovequestion is option5or6,kindlyprovidereason/s: ----------

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*Completed means last patient last visit of study

5. Recruitment status of study participants(Mention details):

1. Total participants to be recruited: ____
2. Screened: ____
3. Enrolled/Randomised: ____
4. Discontinued (with reason): ____
5. Withdrawn:____
6. Screen Failures: ____
7. Completed: ____
8. Active: ____

Comments (if any):

6. Site Facility visit done: Yes ☐ / No ☐

Comments (if any):

7. Informed Consent Process:

1. Type of consent taken:	
a) Consent- Oral & written	Yes ☐ / No ☐
b) Audio visual	Yes ☐ / No ☐
Comments (if any):	
Consent documents are checked for: _____ subjects *(Mention subject no.)*	Sub. No. XX, XX etc.
Check following in case of audio-visual (AV) consent (Please enter if applicable):	
1. Whether recording is conducted in a room conducive to recording (Good light, noise free, privacy ensured)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
2. Whether information is given to the study participant and/or LAR and impartial witness (as applicable) that the process of taking the consent is being recorded?	Yes ☐ / No ☐ / NA ☐
AV recordings are checked for: _____ subjects *(Mention subject no.)*	Sub. No. XX, XX etc.
Comments (if any):	
3. Are all AV recorded CDs are appropriately labelled and stored in password protected laptop/ desktop computer and/ or hard	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
Checkpoint for consent process of children (Please enter if applicable):	
1. Are provisions made to obtain the assent of children of 7 years and above (where appropriate)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	

2. Type of assent taken: (Mention details): For e.g.: a. Oral assent b. Written assent	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
3. Assent documents are checked for: _____ children *(Mention total subject no.)*	Sub. No. XX, XX etc.
Comments (if any):	
4. Are provisions available at site to obtain assent process of children less than 7 years of age (where appropriate)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
5. Are provisions made to protect participants' privacy and the confidentiality of information regarding consent procedures?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Consent from parents is taken?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Is consent of both parents necessary?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
Checkpoint for consent process of pregnant women (Please enter if applicable):	
1. Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions?	Yes ☐ / No ☐ / NA
Comments (if any):	
2. Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably	Yes ☐ / No ☐ / NA
Comments (if any):	
General checkpoint for consent document and consent process	
1. Is the recent version of ICD used for consent is after EC approval?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
2. Whether ICF is signed and dated by subject and by PI?	Yes ☐ / No ☐ / NA ☐

Comments (if any):	
3. Whether copy of ICD was given to patient?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
4. Are source notes of Informed consent process maintained?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
5. Whether any of the informed consent process was observed by EC monitor during monitoring process?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Is there process for obtaining, documenting, recording and maintaining source notes of re-consent process if there are any	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Are all steps taken to ensure privacy and confidentiality of vulnerable participants?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. Is Informed Consent process well documented and there is no undue coercion or incentive for participation?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
9. Whether in case of illiterate subjects or illiterate representative of a subject, there are signature and details of an impartial witness?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
10. Whether witness signature is being personally dated (If applicable)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. <u>Checkpoints related to site master file:</u>	

1. Are all investigators meeting related documents compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
Is recent EC approved version of protocol used? Mention protocol version no. and date:_____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
2. Havethe subsequent protocol amendments been approved by DCGI? Mention approval dates:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
3. Are all regulatory application and approval documents compiled in file i.e. study approval, CTRI registration, financial disclosure?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
4. Are thepresent studyteam members trained on study and GCP requirements?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
5. Whether study contact details of site staff (PI, Co-Investigator/sub-Investigator and CRC) are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Whether Sponsor contact details are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Whether CV, GCP, eCRF training certificate, study document training certificate and MRC of PI are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. Whether CV, GCP, study document training certificate and MRC of co-investigators/sub-investigators/study physicians are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	

9. Whether CV, GCP, eCRF training, study document training certificate (If applicable) of other site staff are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
10. Are delegation log of site staff /study team are present? And Whether they are performing their duties as per delegation log?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
11. Are all version of informed consent documents compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
12. Are all translated and back translated documents compiled in file with translation certificates?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
13. Whether informed consent has been obtained from each subject prior to participation of the subject in study?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
14. Any adverse events found and reported in CRF?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
15. Is CRF up to date and data in CRF corresponds to the source documents (Source file of participant):	Yes ☐ / No ☐ / NA ☐
Comment:	
16. Whether all SAE are reported to EC within timelines specified by NDCT rules 2019?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
17. Are there any SAE? If yes, mention number of SAE occurred at site: _____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
18. Mention the criteria of SAE reported: Death And/or Other than Death	Yes ☐ / No ☐ / NA ☐

Comments (if any):	
19. Whether reported SAEs are related to clinical trial and/or drug:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
20. If related, compensation has been paid as per timelines specified by licensing authority?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
21. Are there emergency facilities available to handle any emergency situation?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
22. Last monitoring /auditing of the site by sponsor/CRO done if any: Date of last monitoring/auditing_____ Follow-up report of monitoring/auditing sent to site_____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
23. Are all monitoring/auditing related reports, other applicable documents and communication filed in site file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
24. Whether lab test/investigations are done from accredited lab? Mention accreditation validity date:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
25. Whether adequate quantity of drug received/dispensed/destroyed with adequate storage conditions along with IP shipment documents?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
26. Are IP storage area are locked or under access control provision?	Yes ☐ / No ☐ / NA ☐

Comments (if any):	
27. Whether adequate record of quantity of test drug received, dispensed, drug accountability log is maintained?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
28. Is IP code breaking process available at site and is documented in study manual in case of blinded study?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
29. Are investigation product containers appropriately labelled? Mention expiry date of IP:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
30. Are all Interactive Web/Voice Response System Manual (IWRS/IVRS), IP manual, IP logs and forms, & Related documents Communication filed in site file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
31. Are electronic or hand-written temperature logs available for investigational products?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
32. Are there any violation/deviation/non-compliance of protocol? If yes then whether the same is notified to EC, sponsor and regulatory authority or not?	Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐
Comments (if any):	
33. Whether travel allowance/reimbursement given to the participant for each visit? a) How much is the travel reimbursement amount as per ICF? Rs. _____ b) Is Visit schedule of participant followed as per protocol?	Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐

Comments (if any):	
34. Is insurance valid: Validity period: _____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
35. Are site SOPs available (Investigator and site)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
36. In case of vaccines, is a spillage SOP available and the study team trained to handle such an incidence?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
37. Are there any new information available that changes risk-benefit analysis reported to EC?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
38. Are source files of all subjects available and are in proper condition to ensure completeness, legibility, accessibility of the documents	Yes ☐ / No ☐ / NA ☐
39. Source notes are checked for: _____ subjects *(Mention subject no.)*	Sub. No. XX, XX etc.
Comments (if any):	
40. Does interaction with PI and study team members happens on regular basis to confirm proper understanding of study activity and uniformity as per protocol?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
41. Whether any participant recruitment process like advertisement, letter, poster, notices were followed?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	

42. Are all study specific logs and forms like screening and enrolment log, subject identification log, site visit log, PD log are compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
43. Whether site has submitted CSR notification to EC after study completion? *(Applicable for only completed studies)*	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
44. Whether site maintains all communications with sponsor, EC and Licensing Authority?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
45. Is adequate space available for document retention and documents are maintained properly for the period as specified?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
46. Whether the archival access controlled or restricted to authorized personnel.	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
47. How well are the participants protected? Good ☐ Fair ☐ Not Good ☐	
Comments (if any):	
48. Any other remarks:	

49. Final remarks by EC monitors:

Note: This EC monitoring checklist can be modified by different Ethics Committees to include additional checkpoints as per study related requirement and can incorporate the EC details (like name, address, institutional affiliation and logo).

	Name	**Sign and Date (DD-MMM-YYYY)**
Checklist filled by*: (EC Monitor-1)		
Checklist filled by: (EC Monitor-2)		
Checklist filled by: (EC Monitor-3)		

8.3. Ann03/SOP16/v1: Site Monitoring Visit Report

SITE MONITORING REPORT	
Name and address of site	**Name:**
Site No.	
Study No.	
Name of Principal Investigator	
Name and Address of EC	
Name and Address of Sponsor	
Site Personnel attended Monitoring activity	
Absent members at Opening Meeting	
Type of Monitoring	

EC Personnel conducted Monitoring activity		
***Date(s) of monitoring activity**		
Time of site Monitoring	Informed start time :	
	Actual Start time-	End time-
***Date of monitoring report**		

Category of Observation:

1) **Study status-**

2) **Recruitment status of study participants:**

Approved by EC -
Screened -
Screen failure -
Ongoing -

Observation	Reason for Screen Failure
Response by PI	

3) **Informed Consent Form**

a) Type of Consent-

Oral and written -

Audio Visual -

Observation	

b) Consent document Checked:
Subject No: -

Observation	

C) Informed consent process observed -

4) Ongoing version of study protocol –

5) Site Master File – (Refer Checklist)

Inclusion and exclusion criteria have been adhered to –

Protocol deviations observed -

Adverse events found -

SAE Found -

Participant safety and wellbeing assured – Yes

6) Provisional Decision – 1. No further action required
2. **Request information**
3. Recommend further action

7) Names of the Site Monitors with signature and date
8) Extract of resolution of minutes YEC-2 meeting No:

Date of the meeting:

9) Final Decision:

1. No further action required
2. Request information
3. Recommend further action

10) Signature of Chairperson with date:

Response provided by:

	Name	Role	Sign and Date (DD-MMM-YYYY)
Response provided by (Site staff)			
Response approved by (Principal Investigator / designee)			

Compliance reviewed by:

	Name	Role	Sign and Date (DD-MMM-YYYY)
Compliance reviewed by (EC monitor)			
Compliance approved by (Member Secretary)			

8.3. Ann04/SOP16/v1: Template for memo

Study No. with version and date	
Study Title	

Name and Address of Site	
Date of filing this document	
Description of Non-Compliance to planned monitoring visits	
Reason of Non-compliance	
Corrective action	
Preventive action	

	Prepared By	**Approved By**
Name	(EC Monitor)	(EC Chairperson)
Role of person		
Signature & Date		

Note:

1. *Follow date convention process as per institution/hospital and this document should be approved by EC chairperson.*

2. This document can be modified by EC per their institution requirement.

8.4. Ann05/SOP16/v1: Roster for Site monitoring (Template)

Month & Year (For e.g.: January 2022)

(Please use separate sheet for next month of the year)

SL. No.	Study Number	Actual EC monitoring visit Dates# (DD-MMM-YYYY)	Type of Monitoring (Please check (X) the applicable box)	EC monitor's Name and Designation*	Monitoring Status	Report Issued Date (Please check (X) the applicable box)
			Onsite monitoring ☐ Remote monitoring ☐ For Cause Monitoring ☐	EC monitor 1: Name: _____ Designation: _____ EC monitor 2: Name:	Completed ☐ Rescheduled on: MMM YYYY# Reason:_____ Cancelled: Reason:_____	Yes ☐ Issued on date: DD/MMM/YYYY# No: ☐ DD/MMM/YYYY# Reason: Not Applicable: Reason:

Note: *This document needs to be updated as and when the activities are completed and can be modified by EC per their institution requirement.*

*****EC monitor's Name and Designation can be added as needed. #Follow date convention as per institution and hospital.

1.4 Ann06/SOP16/v1: Subcommittee for site monitoring

Sr. No.	Name of EC Member	Role of person with EC	*Start date as a EC member	*End date as EC member	*Sign and date
01	ABC	Member Secretary	DD-MMM-YYYY	DD-MMM-YYYY	

8.6. Ann07/SOP16/v1: Detailed flow chart of Site Monitoring