

SITE MONITORING ACTIVITIES

24.02.2024

NAAC Accredited A+ with CGPA 3.47

**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 <i>Leena</i> 24/02/2024
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**Reviewed by:**

Dr. Sridevi K Member, YEC2 SOP Subcommittee	Signature with Date <i>Sridevi</i> 24/02/2024
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**Approved by:**

Dr. Animesh Jain Chairperson , YEC2	Signature with Date <i>Animesh</i> 24/02/24
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**Notified by:**

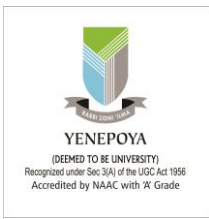
Registrar, Yenepoya(Deemed to be university)	Signature with Date <i>Uthayakumar</i> Registrar YENEPOYA (Deemed to be University) 24/02/24
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**Details of superseded SOP16/v1**

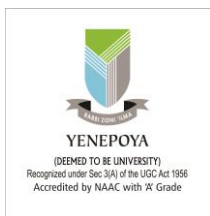
Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

**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

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## 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.

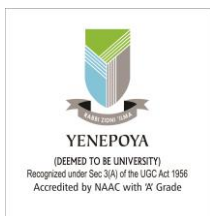
3.1.1. **Routine monitoring:** When the site monitoring is planned at the time of approval of the protocol based on the risk assessment and will include regulated clinical trials, clinical studies involving vulnerable populations, and other interventional studies posing more than minimal risk to the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

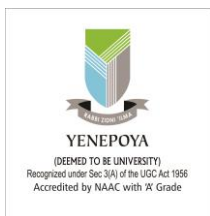
4.3.5. Coordinate with the onsite representative of the PI and the SM subcommittee members for the smooth conduct of the SM

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.”<sup>1</sup>



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.”<sup>2</sup>

5.3 New drugs Clinical trial Rules (2019)<sup>3</sup>:

“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)*<sup>1</sup>

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

*NDCTR (2019)<sup>3</sup> – The Gazette of India : Extraordinary Part II – SEC.3 (I) - Third Schedule Pg 211*

## 6. Detailed instructions:

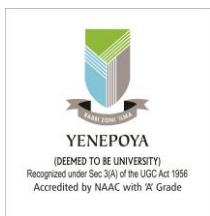
### 6.1. Routine Monitoring

6.1.1 For 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<sup>1</sup>.

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.

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

6.2.3 Large number of Serious Adverse Events (SAE) reports

6.2.4 High 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<sup>2</sup>.

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

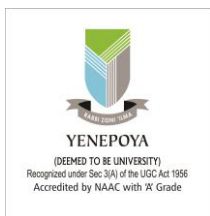
6.2.11 Misconduct by an investigator of a research proposal approved by YEC-2

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.

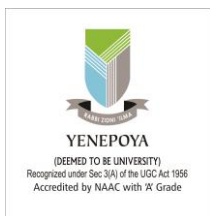
6.4.5 During site monitoring the monitor will follow the checklist (YEC2/ Ann01/SOP16/v1). The monitors will check:

- 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.

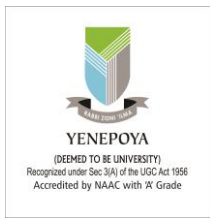
6.5.3 The Member-Secretary will present the monitoring report at the next YEC 2 meeting and the concerned monitor will provide additional details/clarifications to members, as required.

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

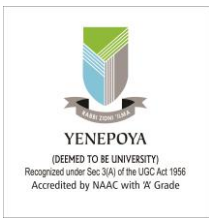
8.4. Ann05/SOP16/v1: Roster for Site monitoring (Template)

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



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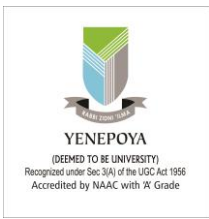
	<p>storage room; other areas.</p> <ol style="list-style-type: none"> <li>2) Meeting with Investigator and Site staff</li> <li>3) Investigator Site Master File review</li> <li>4) Audio-Video consent form review</li> <li>5) Informed Consent Form review</li> <li>6) Source document review</li> <li>7) Investigational product accountability and handling</li> <li>8) Study specific forms and log</li> <li>9) Process of document management/handling at site</li> <li>10) Site SOPs</li> <li>11) Sample collection and processing activity</li> <li>12) Sponsor and Regulatory communication</li> <li>13) AE/SAE documentation (if any)</li> <li>14) Protocol deviations (if any)</li> <li>15) Others i.e. Archival area please specify_____</li> </ol>
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	<b>Prepared By:</b> <b>(By EC monitor)</b>	<b>Approved By:</b> <b>(By EC member secretary)</b>	<b>Acknowledged by:</b> <b>(By site investigator)</b>
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**

<b>Study Number</b>		<b>Name of Department</b>	
<b>Study Title</b>			
<b>Name, address and contact details of site</b>			
<b>Date of study initiation</b>		<b>Date of EC approval</b>	



<b>Date of monitoring visit</b>		
<b>Opening meeting Conducted</b>	Yes <input type="checkbox"/> / No <input type="checkbox"/>	
	Members present during meeting are:	
	<u><b>Name of EC monitors:</b></u>	<u><b>Name of Site members:</b></u>

**1. Type for monitoring :**

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

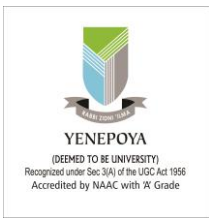
**b) For cause (state reason) – Yes/No**(Please tick mark suitable option)  
(If yes then select applicable below option)

i) High number of protocol violation/deviation ii) 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)

<b>2. Last EC monitoring done, if any:</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Date of last visit: DD/MMM/YYYY	

<b>3. Vulnerable population involved</b> (Tick applicable box)	1. Pregnant women <input type="checkbox"/>	6. Illiterate <input type="checkbox"/>
	2. Children <input type="checkbox"/>	7. Handicapped <input type="checkbox"/>



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	3. Elderly	<input type="checkbox"/>	8. Economically & socially backward	<input type="checkbox"/>
	4. Terminally ill	<input type="checkbox"/>	9. Any Other	<input type="checkbox"/>
	5. Fetus	<input type="checkbox"/>		

**4. Study Status**(Tick applicable box):

1. Ongoing  2. \*Completed  3. Enrollment Completed

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

In case of the response to the above question is option 5 or 6, kindly provide reason/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): \_\_\_\_\_

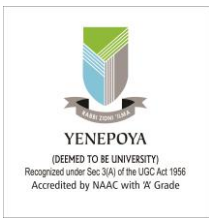
5. Withdrawn: \_\_\_\_\_ 6. Screen Failures: \_\_\_\_\_

7. Completed: \_\_\_\_\_ 8. Active: \_\_\_\_\_

Comments (if any):

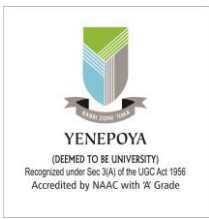
**6. Site Facility visit done:** Yes  / No

Comments (if any):

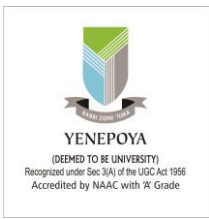


**7. Informed Consent Process:**

<b>1. Type of consent taken:</b>	
a) Consent- Oral & written	Yes <input type="checkbox"/> / No <input type="checkbox"/>
b) Audio visual	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Comments (if any):	
Consent documents are checked for: _____ subjects <i>(Mention subject no.)</i>	Sub. No. XX, XX etc.
<b><u>Check following in case of audio-visual (AV) consent (Please enter if applicable):</u></b>	
1. Whether recording is conducted in a room conducive to recording (Good light, noise free, privacy ensured)?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
AV recordings are checked for: _____ subjects <i>(Mention subject no.)</i>	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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
<b><u>Checkpoint for consent process of children (Please enter if applicable):</u></b>	
1. Are provisions made to obtain the assent of children of 7 years and above (where appropriate)?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	



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

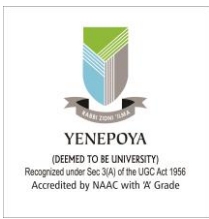


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Comments (if any):	
3. Whether copy of ICD was given to patient?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
4. Are source notes of Informed consent process maintained?	Yes <input type="checkbox"/>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

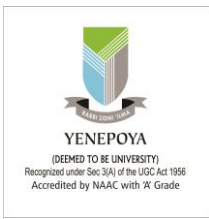




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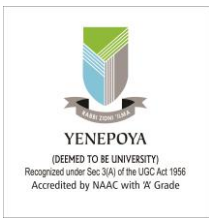
1. Are all investigators meeting related documents compiled in file?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
Is recent EC approved version of protocol used?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>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



SITE MONITORING ACTIVITIES

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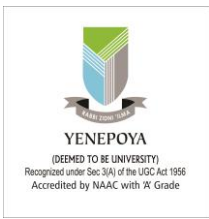
9. Whether CV, GCP, eCRF training, study document training certificate (If applicable) of other site staff are present?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
10. Are delegation log of site staff /study team are present? And Whether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



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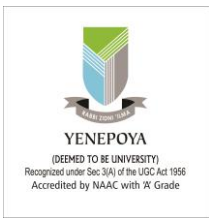
Comments (if any):	
19. Whether reported SAEs are related to clinical trial and/or drug:	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
20. If related, compensation has been paid as per timelines specified by licensing authority?	Yes <input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



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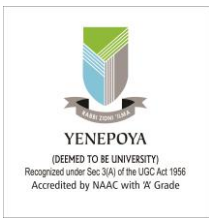
Comments (if any):	
27. Whether adequate record of quantity of test drug received, dispensed, drug accountability log is maintained?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
28. Is IP code breaking process available at site and is documented in study manual in case of blinded study?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
29. Are investigation product containers appropriately labelled?  Mention expiry date of IP:	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
31. Are electronic or hand-written temperature logs available for investigational products?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/> Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/> Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/> Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>



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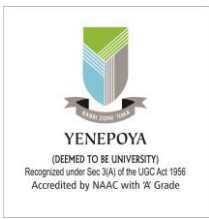
Comments (if any):	
34. Is insurance valid: Validity period: _____	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
35. Are site SOPs available (Investigator and site)?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
36. In case of vaccines, is a spillage SOP available and the study team trained to handle such an incidence?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
37. Are there any new information available that changes risk-benefit analysis reported to EC?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
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 <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	
41. Whether any participant recruitment process like advertisement, letter, poster, notices were followed?	Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/>
Comments (if any):	



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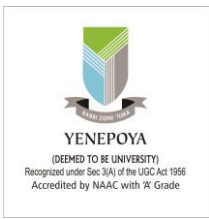
<p>42. Are all study specific logs and forms like screening and enrolment log, subject identification log, site visit log, PD log are compiled in file?</p>	<p>Yes <input type="checkbox"/> / No <input type="checkbox"/> / NA <input type="checkbox"/></p>
<p>Comments (if any):</p>	
<p>43. Whether site has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



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).*

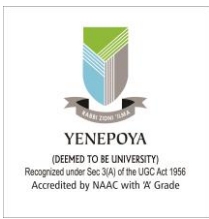
	Name	Sign and Date (DD-MMM-YYYY)
Checklist filled by*: (EC Monitor-1)		
Checklist filled by: (EC Monitor-2)		
Checklist filled by: (EC Monitor-3)		



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

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





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

**Category of Observation:**

**1) Study status-**

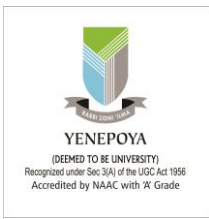
**2) Recruitment status of study participants:**

- 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 -

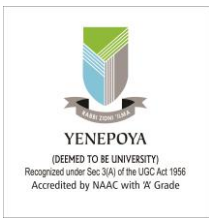
Participant safety and wellbeing assured – Yes

- 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:



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9) Final Decision:

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

10) Signature of Chairperson with date:

Response provided by:

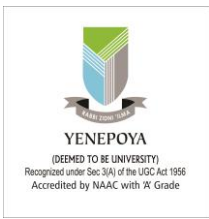
	Name	Role	Sign and Date (DD-MMM-YYYY)
Response provided by (Site staff)			
Response approved by (Principal Investigator / designee)			

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	



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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	

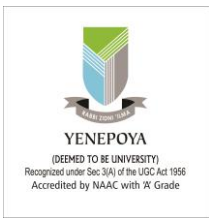
	Prepared By	Approved By
Name	(EC Monitor)	(EC Chairperson)
Role of person		
Signature & Date		

**\*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)



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(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 <input type="checkbox"/> Remote monitoring <input type="checkbox"/> For Cause Monitoring <input type="checkbox"/>	EC monitor 1: Name: _____ Designation: _____  EC monitor 2: Name: _____	Completed <input type="checkbox"/> Rescheduled on: _____ Reason: <u>MMM YYYY#</u> _____ Cancelled: Reason: _____ _____	Yes <input type="checkbox"/> Issued on date: DD/MMM/YYYY# No: <input type="checkbox"/> 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**

