Title: Site Monitoring and Post-Monitoring Activities

SOP Code: SOP16/v2

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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 University Ethics Committees (YUEC) approved protocol.

2. Scope

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

3. 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 YUEC member(s) to perform on-site monitoring of selected study site(s).

4. Mandate:

"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."[1]

5. Detailed instructions:

5.1 Selection of study site(s):

5.1.1 Routine monitoring for a site may be decided at the time of approval of the project by the Ethics Committee at its meeting.

5.1.2 This should be recorded in the YUEC decision form (Ann03/SOP7A/v2) and in the YUEC minutes.

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

5.1.4 The reasons for identifying a particular site for "*for-cause monitoring*" could include

[1] http://www.cdsco.nic.in/html/GCP1.html accessed on 13 July 2016 at 1137 hours
[2] http://cdsco.nic.in/writereaddata/finalAccreditation%20Standards.pdf accessed on 13 July 2016 at 1143 hours

any one or more of the following:

- High number of protocol violations, or frequent violations or violations that significantly and unjustifiably increase the risk burden on the research participants.
- Large number of studies carried out at the study site or by the investigator
- Large number of Serious Adverse Events (SAE) reports
- High recruitment rate
- Frequent failure to submit the required documents
- Non-compliance of the PI to standards of care in research as based on the Indian GCP guidelines.
- Receipt of complaints about the research trial from any stakeholder[3].
- Any other cause as decided by YUEC

5.2 Before the visit

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

5.2.2 The Chairperson will identify and select one or more YUEC members (henceforth referred to as monitor/s) to conduct monitoring of a site. The selected members will be given an appointment letter in this regard

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

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

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

5.2.6 Monitors will carry with them the site monitoring visit report form (Ann01/SOP 16/v2 and Ann02/SOP 16/v2) collected from the Secretariat (if applicable).

[3] http://cdsco.nic.in/writereaddata/finalAccreditation%20Standards.pdf accessed on 13 July 2016 at 1150 hours

5.3 During the visit

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

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

5.3.3 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 15 minutes before returning and file the report stating "Unavailable for monitoring".

5.3.4 Suitable action may be taken by the YUEC in its next meeting in this regard and the same will be minuted and conveyed to the PI.

5.3.5 During site monitoring the monitor will follow the checklist (Ann01/SOP16/v2). He/She/They will check:

- The log of delegation of responsibilities of study team
- Whether the site is using latest YUEC 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

5.3.6 The Monitor will fill the site monitoring visit report form (Ann01/SOP16/v2) and Ann02/SOP16/v2(if applicable), sign and date it.

5.4 After the visit

5.4.1 The Monitor will submit the completed site monitoring visit report form (*Ann01/SOP16/v2 and Ann02/SOP 16/v2 - if applicable*) to the YUEC secretariat within 7 working days of conducting a site monitoring visit or at the time of immediate next meeting of the YUEC (whichever is earlier).

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

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

5.4.4 YUEC 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.

5.4.5 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 5.4.4 will be taken. The final decision taken by the Chairperson, will be informed at the next YUEC meeting and will be recorded in the site monitoring visit report form (*Ann01/SOP16/v2*) and in the minutes.

5.4.6 The Secretariat will convey the decision of the YUEC to the Principal Investigator in writing within 14 working days of the meeting.

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

6. Reference to other applicable SOPs:

SOP7A/v2: Initial Full-Board Review of Research Study Protocols

7. Annexures:

Annexure 1: Ann01/SOP16/v2: Site Monitoring Visit Report

Annexure 2: Ann02/SOP16/v2: Monitoring of Audiovisual recording of AV consent Process

Annexure 1: Ann01/SOP16/v2
Site Monitoring Visit Report

YUEC Proposal No.	Date of visit:
Study Title:	
Name and affiliation of PI:	
Type of Study: Investigator initiated	Sponsored/funded
Date of IEC approval:	
Date of Initiation of the study:	
Duration of study:	

Reason for monitoring: Routine For-cause (state reason): Protocol violations/deviations SAE reporting Recruitment rate Others	
Last monitoring done: Yes/No	Date:
Proper status:	1. Ongoing 2. Completed 3. Recruitment completed 4. Follow up/Extension 5. Suspended 6. Terminated
Recruitment details	1. Recruited (so far) 2. Screened 3. Screen failures 4. Enrolled 5. Withdrawn 6. Reasons for withdrawing 7. Discontinued 8. Reasons for discontinuing 9. Completed 10. Active
Are the present study team members as per the list approved by the YUEC	Yes/No Comment
Are the site facilities appropriate	Yes/No Comment
Is the recent version of Informed Consent Document (ICD), after YUEC approval used?	Yes/No Comment
Whether consent has been taken from all patients in their native language?	Yes/No Comment
Any other findings noted about the ICDs?	Yes/No Comment
Is recent YUEC approved version of protocol used?	Yes/No Comment
Have the eligibility, inclusion exclusion criteria been adhered to?	Yes/No Comment

Any adverse events found?	Yes/No Comment
Any SAEs found?	Yes/No Comment
Were the SAEs informed to YUEC within timelines specified by CDSCO?	Yes/No Comment
No. of deaths reported Deaths unrelated to trial participation Deaths possibly related to trial participation Deaths due to trial participation Any other non-death study-related injury	Comments (if any):
Compensation paid for study related injury or death	Yes/No Comment
Are there any protocol non-compliance deviations/violations?	Yes/No Comment
Have the protocol non-compliance deviations/violations been informed to YUEC?	Yes/No Comment
Are all Case Record Forms up to date?	Yes/No Comment
Are storage of data and investigating products locked?	Yes/No Comment
How well are the participants protected?	Good/Fair/Not good Comment
Any other remarks	Yes/No Comment
Duration of visit:_____ hours	Start time: End time:

Name(s) of the study team member(s) present:	Signature of team member(s) with date
Name(s) of YUEC members who attended monitoring visit:	Signature of YUEC members with date
Completed by:	Signature with date:

Final decision at the YUEC meeting held on (date)	Extract of resolution of minutes:
	Signature of Chairperson with date:

Annexure 2: Ann02/SOP16/v2
Monitoring of Audiovisual recording of Informed Consent Process

Sl No	Checklist item	Response
1	Facility where informed consent process should be carried out is well lit, free from noise, privacy ensured?	Yes/No Comment
2	Is the consent process and the consent form in a language the participant/LAR understands best and is literate in?	Yes/No Comment
3	Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process was done?	Yes/No Comment
4	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?	Yes/No Comment
5	Was information provided to the participant/ LAR/ witness (as applicable) that the confidentiality of information and privacy of participants is assured?	Yes/No Comment
6	Was information provided to the participant/ LAR/ witness (as applicable) that the recording may be shown to government agencies or members from the YUEC?	Yes/No Comment
7	Was explanation or narration provided by the person conducting the informed consent discussion?	Yes/No Comment
8	Were the questions asked by the potential participant/LAR answered satisfactorily?	Yes/No Comment
9	Did the PI allow ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members?	Yes/No Comment

10	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 informed consent and stating whether participant agrees or not for each statement=?	Yes/No Comment
11	Was there appropriate documentation of signatures of all those involved in the informed consent process?	Yes/No Comment
12	Was there adequate clarity and completeness of the AV recording of the informed consent process?	Yes/No Comment
13	Was the recording stored in password protected laptop/desktop computer and/or hard drive and/or labeled CD with access allowed only to the principal investigator and designated members of the study team?	Yes/No Comment

Name(s) of the study team members carrying out the informed consent process with signature and date:

Name(s) of the YUEC monitor(s) observing the informed consent process with signature and date:

Final decision at the YUEC meeting held on (date)	Extract of resolution of minutes:
	Signature of Chairperson with date:

8. Flow Chart

No.	Activity	Responsibility
1	Selection of study sites	Member Secretary / Chairperson
2	Identification of YUEC members for monitoring during meeting	Chairperson
3	Informing Principal Investigator in writing	Secretariat
4	Reviewing of YUEC protocol file prior to visit and collecting site monitoring visit report form from YUEC office	YUEC member
5	Reviewing or monitoring of site	YUEC member
6	Completing the monitoring report and presenting in YUEC meeting	YUEC member
7	Communication of YUEC decision to PI	YUEC Secretariat