**Standard Operating Procedures of Institutional Ethics Committee**

**ICMR – NIRRCH Ethics Committee for Human Studies**

# Title: Site Monitoring Visit

**SOP Code: 21/V1.5** **Dated: 8th November 2024** **Pages: 244 to 250**

**21.1. Purpose**

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored for its performance or compliance to GCP.

**21.2. Scope**

This SOP applies to any visit and/or monitoring of any study sites as stated in the IEC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

**21.3. Responsibility**

It is the responsibility of the IEC to perform or designate some Ethics Committee Members to perform on its behalf on-site inspection of the research projects it has approved.

The IEC members or Secretariat in consultation with the Chairperson may initiate an onsite evaluation of a study site for a cause or for a routine audit.

**21.4. Flow chart**

| **Sr. No.** | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Selection of study sites | IEC members and Chairperson |
| 2 | Procedures before the visit | Member Secretary, Secretariat |
| 3 | Procedures during the visit | IEC members, Member Secretary, Secretariat |
| 4 | Procedures after the visit | IEC members, Member Secretary, Secretariat |
| 5 | Present the findings to the Full Board | IEC members/Member Secretary |

**21.5. Detailed instructions**

**21.5.1 Selection of study sites**

a. Review periodically the files of the submitted/approved study protocols.
b. Selection of the study sites should be done randomly
c. Select study sites needed to be monitored based on the following criteria:
    1. For cause – onsite visit
        i High number of protocol violations/ deviations
        ii Large number of proposals carried out at the study site
        iii Large number of proposals carried out by the same researcher
        iv Large number of SAE reports
        v High recruitment rate
        vi Complains received from participants
        vii Any adverse media report
        viii Adverse information received from any other source

ix Non-compliance with Ethics committee directions
x Misconduct by the researcher
xi Any other cause as decided by Ethics committee

2. Not for cause – No reason, choose any site at random
3. Offsite monitoring – routine checking of progress reports especially those involving high risk and those enrolling vulnerable population

**21.5.2 Before the visit**

The IEC Secretariat only will

a. Contact the site to notify them that they/ their representative will be visiting them. At that time, the monitor(s) and the site will coordinate a time for the site evaluation visit.
b. Make the appropriate travel arrangements.
c. Review the IEC files related to the study and site,
d. Make appropriate notes, or
e. Copy some parts of the files for comparison with the site files.

**21.5.3 During the visit**

a. Get a checklist **AF/01/21/V1.5** (ANNEX 1).
b. The IEC representatives will
   1. Review the informed consent document to make sure that the site is using the most recent version,
   2. Review randomly the participant files to ensure that participants are signing the correct informed consent,
   3. Observe the informed consent process, if possible.
   4. Observe the audio-visual monitoring process, if applicable & possible. (Refer to **AF/01/08/V1.4,** see ANNEX 2 of the SOP 08/V1.4)
   5. Observe laboratory and other facilities necessary for the study at the site.
   6. Review the IEC files for the study to ensure that documentation is filled appropriately.
   7. Collect views of the study participants, if possible.
   8. Get immediate feedback.

**21.5.4 After the visit**

**a. The IEC representative will**

i write a report/comment (use the form **AF/01/21/V1.5,** see ANNEX 1) within 2 weeks describing the findings during the audit
ii forward a copy of the site visits to the Secretariat

**b. The Secretariat will**

i include this report in the Agenda of the Full committee meeting
ii Send a copy of the approved report to the site for their files, and
iii Place the report in the correct site files.

### 21.5.5 Expenditure for the site visit

Expenditure incurred for site visit need to be reimbursed by ICMR-NIRRCH. ICMR-NIRRCH should have some corpus funds to meet the expenses of the site visit. Site visit is done only to oversee ethical conduct of research (and not for the scientific review). The PI should be informed in advance about the site visit.

## 21.6 ANNEX

| | | |
|---|---|---|
| ANNEX 1 | AF/01/21/V1.5 | Checklist of a Monitoring Visit |
| ANNEX 2 | AF/02/21/V1.5 | Document History |

**ANNEX 1** **AF/01/21/V1.5**

**Checklist of a Monitoring Visit**

1. Project No.: □□□/ □□□□
2. Date of the Visit:
3. Study Title:
4. Study Site :
5. Principal Investigator:
    a. Institute:
    b. Address:
    c. Phone:
6. Sponsor:
    a. Address:
    b. Phone:
7. Total number of expected participants:
8. Total participants enrolled:
9. Are site facilities appropriate? □Yes □ No

Comment:

10. Are the EC approved Informed Consent documents used □Yes □No

Comment:

11. Which language are the consent forms filled?
12. Indications for witness signature appropriate?
13. On how many forms did the PI sign?
14. Is consent for storage of samples obtained? □Yes □No

Comment:

15. Any adverse events found? □Yes □No

Comment:

16. Any protocol non-compliance /violation? □Yes □No

Comment:

17. Are all Case Record Forms up to date? Yes No
Comment:

18. Are storage of data and investigational products under lock and key? Yes No
Comment:

19. Are the facilities for data storage secure Yes No
Comment:

20. How well are participants protected? Good Fair Not good
Comment:

21. How is confidentiality maintained ? Yes No
Comment:

22. Infrastructure relevant to study Yes No
Comment:

23. Are PhD students/project staff well versed with ethical issues and documentation?

24. Are all documents submitted and received from EC maintained by the PI?

25. Results of visit? Give details:

26. Duration of visit: …….hours Starting from: Finish:

**Names of IEC members involved in monitoring:**

Completed by: Date:

**ANNEX 2** **AF/02/21/V1.5**

**Document History**

| Author | Version | Date | Description of the Change |
|---|---|---|---|
| Dr. Ragini Kulkarni | Version 1.1 | 24th September 2014 | Bullet 5.1, page no.3 Deleted the point no.6 - In cases where there is no local monitoring by Ethics Committee |
| Dr. Ragini Kulkarni | Version 1.2 | 1st September 2016 | Pg.5, addition of the point 5.5 Expenditure for the site visit<br>Addition under point 5.1 - Addition of the sentence "Selection of the study sites should be done randomly" criteria added - For cause – site for a reasons, too many SAEs, in response to some complaints<br>Not for cause – No reason, choose any site |
| Dr. Ragini Kulkarni | Version 1.3 | 7th November 2017 | Pg. 4, Point 5.3, bullet no. 4 'Observe the audio visual monitoring …… 2 of the SOP 10/V1.2)' added. |
| Dr. Beena Joshi | Version 1.4 | 1st May 2019 | SOP no. changed from 19 to 21<br>5.1, 3rd bullet modified as per ICMR 2017 guidelines<br>Checklist modified |
| Dr. Vikrant Bhor | Version 1.5 | 8th November 2024 | All bullets are numbered.<br>Annex 1 Checklist for monitoring site visit is modified |