Title: Site Monitoring Visit

SOP Code: SOP/19/V1.2

Effective date: 01/09/2016

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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.

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.

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.

No.	Activity	Responsibility
1	Selection of study sites ↓	IEC members and Chairperson
2	Procedures before the visit ↓	IEC members and/or representative
3	Procedures during the visit ↓	IEC members and/or representative
4	Procedures after the visit ↓	IEC members and/or representative
5	Present the findings to the Full Board	IEC members and/or representative

4. Flow chart

5. Detailed instructions

5.1 Selection of study sites

- Review periodically the files of the submitted/approved study protocols.
- Selection of the study sites should be done randomly
- Select study sites needed to be monitored based on the following criteria:
  - New study sites wherever necessary
  - Reports of remarkable serious adverse events
  - Number of studies carried out at the study sites.
  - Non-compliance or suspicious conduct
  - Failure to submit annual reports periodically as decided by IEC.

- For cause – site for a reason, too many SAEs, in response to some complaints
- Not for cause – No reason, choose any site

5.2 Before the visit

The IEC Members only will

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

5.3 During the visit

- Get a checklist AF/EC/01/19/V1.1 (ANNEX 1).
- The IEC representatives will
  - Review the informed consent document to make sure that the site is using the most recent version,
  - Review randomly the subject files to ensure that subjects are signing the correct informed consent,
  - Observe the informed consent process, if possible,
  - Observe laboratory and other facilities necessary for the study at the site.
  - Review the IEC files for the study to ensure that documentation is filed appropriately.
  - Collect views of the study participants, if possible
  - Brief the full board visit report/comments.
  - Get immediate feed back.

5.4 After the visit

- The IEC representative will
  - write a report/comment (use the form AF/EC/01/19/V1.2, see ANNEX 1) within 2 weeks describing the findings during the audit
  - forward a copy of the site visit to the Secretariat
- The Secretariat will
  - include this report in the Agenda of the Full Board meeting
  - Send a copy of the approved report to the site for their files, and
  - Place the report in the correct site files.

5.5 Expenditure for the site visit

Expenditure incurred for site visit need to be reimbursed by NIRRH. NIRRH should have some corpus funding to meet the expenses of the site visit. Site visit is done only for ethical purpose (and not for the scientific review). The PI should be informed in advance about the site visit.

6. Glossary

IEC representatives: Many IEC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IEC.

Monitoring visit: An action that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. References

7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8. ANNEX

ANNEX 1	AF/EC/01/19/V1.2	Checklist of a Monitoring Visit
ANNEX 2	AF/EC/02/19/V1.2	Document History

ANNEX 1 **AF/EC/01/19/V1.2**

Checklist of a Monitoring Visit

Application No.: ☐☐☐ / ☐☐ - ☐☐ Date of the Visit:

Study Title:

Study Site :

Principal Investigator: Phone:

Institute: Address:

Sponsor: Address:

Total number of expected subjects: Total subjects enrolled:

Are site facilities appropriate? Comment:

☐ Yes ☐ No

Are the Informed Consent documents approved by EC are used Comment:

☐ Yes ☐ No

Any adverse events found? Comment:

☐ Yes ☐ No

Any protocol non-compliance /violation? Comment:

☐ Yes ☐ No

Are all Case Record Forms up to date? Comment:

☐ Yes ☐ No

Are storage of data and investigational products under lock and key? Comment:

☐ Yes ☐ No

Are the facilities for data storage are locked Comment:

☐ Yes ☐ No

How well are participants protected? Comment:

☐ Good ☐ Fair ☐ Not good

How is confidentiality maintained ? Comment:

☐ Yes ☐ No

Infrastructure relevant to study Comment:

☐ Yes ☐ No

Results of visit? Give details:

☐ Yes

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

Name of IEC member and accompanion:

Completed by: Date:

ANNEX 2 **AF/EC/02/19/V1.2**

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 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 Not for cause – No reason, choose any site