Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -15/01)

For

Site Monitoring Visit

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select a site for monitoring and how the site will be monitored.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the Independent Ethics Committee (IEC) approved study protocols.

3. Responsibility

It is the responsibility of the IEC members to perform or designate some qualified agents to perform on its behalf on-site inspection of selected study sites of relevant projects it has approved.

The Independent Ethics Committee members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	IEC members / Chairperson
2	Before the visit	IEC members / representative
3	During the visit	IEC members / representative
4	After the visit	IEC members /representative

5. Detailed instructions

5.1 Selection of study sites

- Sites will be identified for routine monitoring at the time of approval of the project by the Full Board which will be recorded in the IEC Decision Form *AF/02/01-SOP06/01*.
- For cause monitoring will be performed at sites for reasons identified by any member of IEC, approved by Chairperson. For cause monitoring could be initiated, in any of the following

conditions: for high number of protocol violations, large number of studies carried out at the study sites, remarkable SAE reports, high recruitment rate, Non-compliance or suspicious conduct and any other cause as decided by IEC.

5.2 Before the visit

- If the site was identified for routine monitoring, the Secretariat will inform the IEC members in the Full Board meeting, 1 month prior to the stipulated date of monitoring.
- For cause/routine monitoring of the project, the IEC Chairperson will designate an IEC member or appoint an Independent monitor to perform the task of monitoring.
- The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation letter from the Principal Investigator to be available for the monitoring visit.
- The IEC member/Independent monitor will also:
  - Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.
  - The Secretariat will make the appropriate travel arrangements for the IEC member/Independent monitor.
  - The IEC member/Independent monitor will review the IEC project files for the study and site profile and make appropriate notes.
  - The IEC member/Independent monitor will copy some parts of the IEC project files for comparison with the site files and collect the Site Monitoring Visit Report Form *AF/01/01-SOP15/01* from the Secretariat.

5.3 During the visit

- The IEC member/Independent monitor 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, if possible.
  - Review the project files for the study to ensure that documentation is filed appropriately.
  - Collect views of the study participants, if possible.
  - Fill the Site Monitoring Visit Report Form *AF/01/01-SOP15/01*and write the comments.

Independent Ethics Committee (Clinical Research) India

5.4 After the visit

- The IEC member/ Independent monitor will complete the report (use the form *AF/01/01-SOP15/01*) within 2 weeks describing the findings of the monitoring visit and during the Full Board meeting present them. If the Independent monitor is unable to attend the IEC meeting he/she can courier the Monitoring Visit Report with comments and the IEC Secretary can present the same.
- The Secretariat will place the report in the correct site files.
- Full board recommendations to change the study/ premature termination/ continuation of the project will go to the Principal Investigator in writing within 10 days of the meeting.

6. Glossary

Independent Consultants	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

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 24 March 2008)

8. Annex

ANNEX 1 AF/01/01-SOP15/01 Site Monitoring Visit Report

Independent Ethics Committee (Clinical Research) India

Annex 1
AF/01/01-SOP15/01

Site Monitoring Visit Report

IEC project .: FFF / FF - FF	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Site:
Sponsor:	
Total number of subjects enrolled:	Total subjects ongoing:
No. of subjects completed:	No. of drop outs:
Are site facilities appropriate? F Yes F No	Comment:
Are Informed Consents of recent version used? F Yes F No	Comment:
Is it approved by the IEC? F Yes F No	Comment:
Whether consent has been taken from all patients? F Yes F No	Comment:
Whether appropriate vernacular consent have been taken? F Yes F No	Comment:
Are Protocols of recent version used? F Yes F No	Comment:
Is it approved by the IEC? F Yes F No	Comment:

Independent Ethics Committee (Clinical Research) India

Any adverse events found? F Yes F No	Comment:
Any SAEs found? F Yes F No	Comment:
Were the SAEs informed to IEC within 7 working days ? F Yes F No	Comment:
Any protocol non-compliance /violation? F Yes F No	Comment:
Are all Case Record Forms up to date? F Yes F No	Comment:
Are storage of data and investigating products locked? F Yes F No	Comment:
How well are participants protected? F Good F Fair F Not good	Comment:
Any outstanding tasks or results of visit? F Yes F No	Give details:
Duration of visit: …….hours	Starting from: Finish:
Name of IEC/ representatives and accompanion:	
Completed by:	Date: