Title: Site Monitoring Visit

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Table of Contents:

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 Institutional Review Board (IRB) approved study protocols.

3. Responsibility

It is the responsibility of the designated IRB member(s) or designated qualified agent to perform on-site inspection of selected study site(s) of relevant projects it has approved.

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

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	IRB members / Chairperson
2	Identification of monitors for site monitoring	Chairperson
2	Before the visit	IRB members / representative, Secretariat
3	During the visit	IRB members / representative
4	After the visit	IRB members /representative, Secretariat

5. Detailed instructions

5.1 Selection of study sites

- IRB will identify the site(s) for routine monitoring at the time of approval of the project depending upon the reason provided by any IRB member. This decision will be recorded in the IRB Decision Form - *AX 03/SOP 06/V3.2*.
- The Chairperson will identify and designate one or more IRB members or independent monitor to carry out routine monitoring of the study site.
- The reason for identifying a particular site for 'monitoring' will be provided to an IRB member. This cause could include any one or more of the following:
  - High number of protocol violations, or
  - Large number of studies carried out at the study site or by the investigator, or

- Remarkable number of SAE reports, or
- High recruitment rate, or
- Non-compliance, or
- Suspicious conduct, or
- Complaints received from participants, or
- Any other cause as decided by IRB.

- After discussion at an IRB meeting, decision regarding conducting 'monitoring' will be taken. The Chairperson will identify and select one or more IRB members or independent monitor to conduct monitoring of a site.

5.2 Before the visit

- The IRB Chairperson will designate an IRB member or appoint an Independent monitor to perform the task of monitoring. The selected member or independent monitor will be provided with an appointment letter in this regard. A copy of the appointment letter along with the agenda for monitoring (mentioned in SOP 15 Version 3.1 point no. 5.3) will be forwarded to the Principal Investigator of the site to be monitored. The independent monitor will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.
- The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator to be available for the monitoring visit.
- The IRB member(s)/ Independent monitor will:
  - 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 IRB member/Independent monitor will review the IRB project files for the study and site profile and make appropriate notes.
  - The IRB member/Independent monitor will be provided with relevant reference material/ documents related to the project that may have to be referred to during the study visits and collect the Site Monitoring Visit Report Form- AX 01/SOP 015/V3.2 from the Secretariat.

5.3 During the visit

- The IRB member/Independent monitor will
  - ✓ Check the log of delegation of responsibilities of study team
  - ✓ Check if the site is using latest IRB approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.

- ✓ Review the informed consent document to make sure that the site is using the most recent version,
- ✓ Observe the informed consent process, if possible,
- ✓ Review randomly selected participants files to ensure that participants are signing the correct informed consent,
- ✓ Observe laboratory and other facilities necessary for the study at the site, if possible.
- ✓ Review the project files of the study to ensure that documentation is filed appropriately.
- ✓ Review the source documents for their completeness.
- ✓ Collect views of the study participants, if possible.
- ✓ Fill the Site Monitoring Visit Report Form- *AX 01/SOP 015/V3.2*, sign and date it.

5.4 After the visit

- The IRB member/ Independent monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 015/V3.2 to* the IRB secretariat within *14 days* of conducting a site monitoring visit.
- The report should describe the findings of the monitoring visit. The member-secretary will present the monitoring report at the next full board IRB meeting and the concerned IRB member/ independent monitor will provide additional details/ clarifications to members, as required.
- The IRB will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - ➢ Continuation of the project with or without changes,
  - ➢ Restrictions on enrollment,
  - ➢ Recommendations for additional training,
  - ➢ Recruiting additional members in the study team,
  - ➢ Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
  - ➢ Suspension of the study, etc.
- The final decision taken at the full board IRB meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 015/V3.2*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

6. Glossary

Independent Consultants/ Independent monitor	Many IRB rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of IRB to perform the tasks on their behalf and later report their findings to IRB.
Monitoring visit	An action that IRB or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of participants, 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 September 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 September 2008)

8. Annexure

Annexure 1 *AX 01/SOP 15/V3.2* Site Monitoring Visit Report

Annexure 1

AX 01/SOP 15/V3.2

Site Monitoring Visit Report

IRB project no.	Date of the Visit:
Study Title:	
Principal Investigators:	
Department:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs including reasons:
Are the present study team members as per the list approved by the IRB ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is recent version of Informed Consent Document (ICD) used? ☐ Yes ☐ No	Comment:
Is it approved by the IRB? ☐ Yes ☐ No	Comment:
Whether consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been used? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs ☐ Yes ☐ No	Comment:
Is recent version of protocol used? ☐ Yes ☐ No	Comment:
Is it approved by the IRB? ☐ Yes ☐ No	Comment:

Any adverse events found? ☐ Yes ☐ No	Comment:
Any SAEs found? ☐ Yes ☐ No	Comment:
Were the SAEs informed to IRB within 7 working days? ☐ Yes ☐ No	Comment:
Any there any protocol non-compliance deviations/violations? ☐ Yes ☐ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IRB ☐ 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 participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit:_____hours	Starting from: Finish:
Name of IRB members and representatives who attended the monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IRB meeting held on _____

_____

Signature with date

Chairperson, IRB