Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -12/01)

For

Protocol Deviation/Non-Compliance/Violation

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for taking action and maintaining records that identify investigators/trial sites that fail to:

- Follow the procedures written in the approved protocol,
- Comply with national / international guidelines or procedures mandated by the Independent Ethics Committee (IEC) for the conduct of Clinical research
- Respond to the IEC requests regarding statutory, ethical, scientific or Administrative matters

2. Scope

This SOP applies to all IEC approved research protocols involving Clinical subjects.

3. Responsibility

It is the responsibility of the IEC members/Chairperson to review and take action in the Full Board meeting. The designated member of the Secretariat is responsible for collecting and recording the Deviation/Non-compliance/Violation list (*AF/01/01-SOP12/01*)

4. Flow chart

No.	Activity	Responsibility
1	Detection of Protocol deviation / non-compliance / violation	IEC members / Secretariat
2	Noting protocol deviation / non-compliance / violation by the Secretariat	IEC members / Secretariat
3	Board discussion, decision and action	IEC members and Chairperson
4	Notify the Principal Investigator	IEC Secretariat, members and Chairperson
5	Keep records and follow up	IEC Secretariat

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5. Detailed instructions

5.1 Detection of Protocol deviation/ non-compliance/ violation

The Protocol deviation/non-compliance/violation can be detected in any of the following ways :

1. The Independent Ethics Committee members performing monitoring of the project at trial site can detect protocol deviation/non-compliance/violation as the project may not be conducted as per protocol/as per national/international regulations.
2. The Secretariat can detect protocol deviation/non-compliance/violation from failure to comply with statutory requirements/failure to respond to requests from Independent Ethics Committee within reasonable time limit/failure to respond to communication made by Independent Ethics Committee.
3. The Principal Investigator himself may forward protocol deviation/non-compliance/violation reports to inform the Independent Ethics Committee.

5.2 Noting protocol deviation / non-compliance / violation by the Secretariat

- The IEC members who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the Secretariat.
- The Administrative Officer will also include protocol deviation/non-compliance/violation from the project files/protocol deviation/non-compliance/violation letters forwarded by the Principal Investigator.
- Whenever protocol deviation / non-compliance / violation has been observed the Secretariat will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the Full Board Independent Ethics Committee meeting.

5.3 Board discussion, Decision and Action

- If the protocol deviation / non-compliance / violation is detected by IEC member during monitoring visit he/she will present the protocol deviation / non-compliance / violation information.
- If detected by Secretariat/forwarded by Principal Investigator, the Secretary will present the protocol deviation / non-compliance / violation information.
- The Chairperson/IEC members will review and will take any one of the following action in ‘consensus’.
  - Request the Principal Investigator not to perform such deviations/non-compliances/violations in future and follow Independent Ethics Committee recommendations.
  - Suspend the study till information available
  - Terminate approval of the current study

- Refuse subsequent applications from an investigator cited for non-compliance.

- The IEC will take appropriate action depending upon the nature and severity of deviation / non-compliance/violation.
- This action is recorded on *AF/01/01-SOP12/01* by the Member Secretary.

5.4 Notify the Principal Investigator

- The Secretariat will send a recommendation letter signed by the Independent Ethics Committee Chairperson to the Principal Investigator if the decision was 'request the Principal Investigator not to perform such deviations/non-compliances/violations in future'.
- The Secretariat will send a project suspension/termination letter signed by the Independent Ethics Committee Chairperson to the Principal Investigator if the decision was 'suspend the study till information available/terminate approval of the current study'.
- If the decision was 'refusal of subsequent project applications from the Principal Investigator, this notification letter signed by Independent Ethics Committee Chairperson will be sent to the Principal Investigator.
- The copy of Project suspension/ project termination/ Principal Investigator notification of refusal to accept application from him/her due to Non-compliance will also be sent to the DCGI/Sponsor.
- One copy of all the letters is kept in the project file by the Secretariat.

5.5 Keep records and follow up

- The Secretariat will maintain a file that identifies investigators who are found to be non-compliant at monitoring visits or with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC request for information/action.
- The Administrative Officer will keep a copy of all the letters in the "non-compliance" file. Store the file in the shelf with an appropriate label and follow up the action after a reasonable time.

6.Glossary

Non-compliance / Violation	The IEC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FDA regulations and/or fail to respond to the IEC request for information/action.

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7. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (lastaccessed 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 AF01/01-SOP12/01 Deviation/Non-Compliance/Violation Record

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Annex1
AF/01/01-SOP12/01

Deviation / Non-Compliance / Violation Record

IEC Protocol no.: FFF / FF - FF	IEC meeting Date: ……
Study Title:	
Investigator:	Contact No.:
Trial site:	
Sponsor:	Contact No.:
F Deviation from protocol { Major { Minor	F Non-Compliance F Violation
Description:	
Found by:…….	Reported by:…….
Date:…….	Date:…….

IEC Actions taken:

F Request the Principal Investigator not to perform such deviations/non compliances/violations in future and follow Independent Ethics Committee recommendations.
F Suspend the study till information available
F Terminate approval of the current study
F Refuse subsequent applications from an investigator cited for non-compliance.

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Sign of IEC Chairperson