Title: Intervention in Protocol Deviation/Non-compliance/Violation

SOP Code: SOP/16/V1.2

Effective date : 07/11/2017

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1. Purpose

To provide instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national / international guidelines for the conduct of human research, including those who fail to respond to the IEC requests.

2. Scope

This SOP applies to all IEC approved research protocols involving human participants.

3. Responsibility

The designated member of the Secretariat is responsible for collecting and recording the noncompliance list (AF/EC/01/16/V1.2).

4. Flow chart

No.	**Activity**	**Responsibility**
1	Noting protocol deviation / noncompliance / violation ↓	IEC members and Chairperson
2	Ethics Committee's discussion and decision ↓	IEC members and Chairperson
3	Notify the investigator ↓	IEC Secretariat, members and Chairperson
4	Keep records and follow up	IEC Secretariat

5. Detailed instructions

5.1 Whenever protocol deviation / non-compliance / violation has been observed:

- Ensure that the project in which non-compliance has been observed is included in the agenda of the IEC meeting.
- Maintain a file that identifies projects that are found to be non-compliant with national/international regulations or investigators who fail to follow protocol approval stipulations or fail to respond to the IEC request for information/action.

- *Note*: The Ethics Committee shall withhold at their discretion the approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

5.2 The IEC Decision

The Chairperson notifies the investigator regarding the IEC's action in writing, when the full board Ethics Committee withholds at their discretion the approval of current studies or refuse subsequent applications from the investigators cited or refuses subsequent applications from an investigator cited for noncompliance. Retraining of the study team members may be recommended if required.

5.3 Notify the investigator

- The IEC Secretariat members record the IEC's decision.
- Draft and type a notification letter.
- Request the Chairperson to sign and date the letter.
- Make four copies of the notification letter.
- Send the original copy of the notification to the investigator.

5.4 Keep records and follow up

- Keep a copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Follow up the action after a time period as suggested by the Ethic Committee.

6. Glossary

Deviation / 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 IECs request for information/action.

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 (ICHGCP) 1996.

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

8. ANNEX

ANNEX 1 AF/EC/01/16/V1.2 Deviation/Non-Compliance/Violation Record

ANNEX 2 AF/EC/01/16/V1.2 Document History

ANNEX 1 **AF/EC/01/16/V1.2**

Deviation / Non-Compliance / Violation Record

Application Number: ☐☐☐ / ☐☐ - ☐☐ Date:……

Study Title:

Investigator

Contact No.:

Institution:

Contact No.:

Sponsor:

Contact No.:

☐ Deviation from protocol

☐ Impact of the deviation on patient safety / data credibility

☐ Non-Compliance

○ Major ○ Minor ☐ Violation

Description:

IEC Decision:

Actions taken:

Outcome:

Reported by:…….

Date:…….

ANNEX 2 **AF/EC/02/16/V1.2**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	SOP no. changed from SOP 11 to SOP 16
Dr. Ragini Kulkarni	Version 1.2	7th November 2017	Added the line in 5.2 'Retraining of the study team members may be recommended if required'. Added in ANNEX 1 'Impact of the deviation on patient safety/data credibility'