5.1. Intervention in Protocol Deviation/Non-compliance/ Violation

Table of Contents

1. Purpose

This SOP is 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 IRB's requests.

2. Scope

This SOP applies to all IRB approved research protocols involving human subjects.

3. Responsibility

The designated member of the Secretariat is responsible for collecting and recording the non-compliance list (EPHI-IRB AF 01-017/02.0).

4. Flow chart

No.	Activity	Responsibility
1	Noting protocol deviation / non-compliance / violation.	IRB and Chairperson
	↓	
2	Board discussion and decision	IRB and Chairperson
	↓	
3	Notify the investigator	IRB Secretariat and/or Chairperson
	↓	
4	Keep records, follow up and report to IRB	IRB Secretariat

5. Detailed instructions

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

- Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IRB meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IRB's request for information/action.

- *Note*: The Board may decide to take no action or propose a need for corrective action plan, suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

5.2. The IRB's Decision

- The chairperson notifies the investigator of the IRB's action in writing, when the Board
- No Further Action Required,
- Request Information, and
- Recommend Further Action

5.3. Notify the investigator

- The IRB Secretariat members record the IRB's decision.
- Draft and type a notification letter.
- Get the Chairperson to sign and date the letter.
- Make six copies of the notification letter.
- Send the original copy of the notification to the investigator.
- Send a copy of the notification to the relevant national authorities and institutes.
- Send the third copy to the director general or deputy director general of EPHI.
- Send the fourth copy to the sponsor or the sponsor's representative of the study.

5.4. Keep records, follow up and report to IRB

- Keep the last 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 reasonable time.
- Report the outcome of the action to IRB.

6. Glossary

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

Major non-compliance — A major violation/non-compliance; is one that may impact on the participant safety or affects the integrity of the study data.

A major protocol violation and/or serious/continuing non-compliance includes but is not limited to any violation that meets ANY of the following criteria:

- Represent a **serious*** failure on the part of the study team to comply with the protocol, standard operating procedures, GCPs, federal, state or local regulations. The violation may not be intentional.
- Represents a **continuing**** failure on the part of the study team to comply with the protocol, standard operating procedures, GCPs, federal, state or local regulations. The violation may not be intentional.
- Significant negative impact to subject safety or alters risks to subjects (increased risk is deemed greater than minimal risk). Note the violation/noncompliance may or may not result in actual harm to the subjects. Risk or actual harm may be clinical, emotional social, financial, etc. (The risk/potential risk to the subject present by this violation is deemed to be greater than minimal risk)
- Significantly damages the completeness, accuracy and reliability of the data collected for the study.

**Serious failure* to comply is non-compliance that adversely affects the rights and welfare of participants or places participants at increased risk of harm.

***Continuing failure to comply* is a pattern of non-compliance that indicates an unwillingness to comply or a lack of knowledge that may lead to an adverse effect on the rights and welfare of participants or may place participants at an increased risk of harm.

Minor non-compliance — A minor violation/non-compliance is one that does not impact on the subjects' safety or compromise the integrity of study data. However, if left unreported could lead to more major violations /non-compliance issues further down the line.

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.

8. Annex

Annex 1: Deviation / Non-Compliance/Violation Record Form
(EPHI-IRB AF 01-017/02.0)

Protocol Number: EPHI-IRB-☐☐☐-☐☐☐☐	Date: ……
Study Title:	
Principal Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:

☐ Deviation from protocol ○ Major ○ Minor	☐ Non-Compliance ☐ Violation
Description:	
IRB's Decision: ☐ No Further Action Required ☐ Request Information ☐ Recommend Further Action	
Actions taken:	Outcome:

Found by: …… Date: …….	Reported by: ……. Date: …….