CHAPTER 5.1

INTERVENTION IN PROTOCOL DEVIATION/NON-COMPLIANCE/VIOLATION

SOP NUMBER: SOP/017/01

INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

The purpose of this SOP shall be 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 shall apply to all IRB approved research protocols involving human subjects.

3. RESPONSIBILITY

The designated member of the Secretariat shall be responsible for collecting and recording the deviation / non-compliance / violation list, ANNEX - AF/01-017/01. It shall be the responsibility of the IRB to review the issues and make decisions.

4. FLOW CHART

No.	Activity	Responsibility
1	Note Protocol deviation / non-compliance / violation. ↓	Primary Reviewers and Chairperson
2	Board discussion and decision ↓	IRB members and Chairperson
3	Notify the investigator ↓	IRB Secretariat, members and Chairperson
4	Keep records and follow up	IRB Secretariat

5. DETAILED INSTRUCTIONS

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

5.1.1. Ensure that the issues as well as the details of non-compliance involving research investigators as commented by the primary reviewers shall be included in the agenda of the IRB meeting.

5.1.2. 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.

5.2. The IRB's Decision

5.2.1. The Board shall discuss and make the decision during the meeting. Such decisions shall be recorded in the minutes.

5.2.2. The chairperson shall notify the investigator of the IRB's decision in writing, when the Board

5.2.2.1. suspends further enrolment of research participants,

5.2.2.2. terminates approval of a current approved study,

5.2.2.3. request for additional information, or

5.3. Notify the investigator

5.3.1. The IRB Secretariat members shall record the IRB's decision.
5.3.2. Draft and type a notification letter.
5.3.3. Get the dated signature of the Chairperson on the letter.
5.3.4. Make adequate copies of the notification letter.
5.3.5. Send the original copy of the notification to the principal investigator.
5.3.6. Send a copy of the notification to the relevant national authorities and institutes.
5.3.7. Send a copy to the sponsor or the sponsor's representative of the study, if applicable.

5.4. Keep records and follow up

5.4.1. Keep a copy of the notification letter in the "deviation / non-compliance / violation" file.
5.4.2. Store the file in the shelf with an appropriate label.
5.4.3. Follow up with the PI after a reasonable time from the issuance of the notification.

6. GLOSSARY

Deviation / Non-compliance / Violation	The Principal Investigator/s do not perform the study in compliance with the originally approved protocol, ICH GCP, DRA, FDA regulations and/or fails to respond to the IRB's 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 (ICH GCP) 2016.
7.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants Guidance document, 2011

8. ANNEX

ANNEX 1 AF/01-017/01 Deviation/Non Compliance/Violation Record

ANNEX 1
AF/01-017/01

Deviation / Non-Compliance / Violation Record

Protocol Number:	Date:……
Study Title:	
Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:

☐ Deviation from protocol ○ Major ○ Minor	☐ Non-Compliance ☐ Violation
Description:	
IRB's Decision:	
Actions taken:	Outcome:

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