CHAPTER 5.3

MANAGEMENT OF STUDY TERMINATION

SOP NUMBER: SOP/019/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Author: SOP Team — Date: September 29, 2021
Approved by: Chairperson, IRB — Date: September 30, 2021
Name: ***Dr. Karma Tenzin***

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1. PURPOSE

This procedure describes how an IRB shall proceed and manage the termination of an approved research study. Protocols are usually terminated at the recommendation of the IRB members, institute heads, sponsor, PI, DSMB or other authorized bodies when subject enrolment and subject follow-up are discontinued before the scheduled end of the study, **when the IRB has observed gross violation of the approved terms and condition of the study**, when it is certain that the approved study can no longer be feasible to carry on due to changes in legal, political or economic circumstances, or when the safety or benefit of the study participants is doubtful or at risk.

2. SCOPE

This SOP shall apply to any study approved by IRB that is being recommended for termination before its scheduled completion.

3. RESPONSIBILITY

The IRB shall be responsible to terminate any study that the IRB has previously approved when subject enrolment and subject follow-up are discontinued before the scheduled end of the study, when the IRB has observed gross violation of the approved terms and condition of the study, when it is certain that the approved study can no longer be feasible to carry on due to changes in legal, political or economic circumstances, or when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive recommendation for study termination ↓	Investigator and IRB Secretariat
2	Review and Discuss the Termination Package ↓	Secretariat and IRB
3	Notify the Principal Investigator ↓	IRB Secretariat
4	Store the Protocol Documents ↓	IRB Secretariat
5	Inactivate the Protocol Document	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive recommendation for study termination.

5.1.1. Receive recommendation and comments from IRB members, institute heads, sponsor, PI, DSMB or other authorized bodies for approved study protocol termination.

5.1.2. Inform the principal investigator or the study office to prepare and submit a protocol termination package.

5.1.3. Receive the study protocol termination package prepared and submitted by the principal investigator or the study office.

5.1.4. Verify the contents of the package for inclusion of:

5.1.4.1. Request for Termination Memorandum, ANNEX- AF/01-019/01

5.1.4.2. The request for termination memorandum should contain a brief written summary of the protocol, its results, and actual data.

5.1.4.3. Original Continuing Review Application Form, ANNEX – AF/01-015/01

5.1.4.4. Termination is indicated under “Action Request”.

5.1.4.5. Completeness of the information, including actual data since the time of the last continuing review.

5.1.4.6. Presence of the required signatures (Principal Investigator).
5.1.4.7. Initial and date the package upon receipt.

5.2. Review and discuss the Termination Package.

5.2.1. Notify the Chairperson regarding the recommendation for study protocol termination.
5.2.2. Send a copy of the termination package to the Primary Reviewers within one working day upon receipt.
5.2.3. The Chairperson shall review the results, reasons and accrual data.
5.2.4. The Chairperson shall call for an emergency meeting to discuss about the recommendation.
5.2.5. The Chairperson shall sign and date the Continuing Review Application Form in acknowledgment and approval of the termination.
5.2.6. The Chairperson shall return the form back to the Secretariat within 5 working days of receipt of the package.
5.2.7. The Secretariat shall review, sign, and date the Continuing Review Application Form indicating that the termination process is complete.

5.3. Notify the Principal Investigator.

5.3.1. Make a copy of the completed Continuing Review Application Form
5.3.2. Send the copy to the principal investigator for their records within 7 working days.

5.4. Store the protocol documents.

5.4.1. Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
5.4.2. Send the file to archive.
5.4.3. Store the protocol documents indefinitely.

5.5. Inactivate the protocol documents.

5.5.1. Place the study protocol into the inactive protocol folder in the computer records under the following directory:
5.5.2. F:\studyfiles\inactive protocols

6. GLOSSARY

DSMB	Data Safety Monitoring Board constitutes a group of scientific people formed for every major study that is done to monitor the data handling.

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
7.4. Associated SOP: SOP/015/01

8. ANNEX

ANNEX 1 AF/01-019/01 Termination Memorandum

ANNEX 1
AF/01-019/01

Study Termination Memorandum

PROTOCOL NUMBER:		PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
IRB APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
REASON FOR TERMINATION			
SUMMARY OF RESULTS			
ACCRUAL DATA:			
P.I.SIGNATURE:		DATE:	