

CHAPTER 8.3

COMMUNICATION RECORDS

SOP NUMBER: SOP/024/01



INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Table of Contents

No.	Content	Page No.
1.	PURPOSE.....	3
2.	SCOPE.....	3
3.	RESPONSIBILITY	3
4.	FLOW CHART	3
5.	DETAILED INSTRUCTIONS.....	3
6.	ANNEX.....	3
	ANNEX 1	4

1. PURPOSE

The purpose of this SOP shall be to ensure proper completion, distribution and filing of verbal and written communication and other study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies.

2. SCOPE

This SOP shall apply to all communicating activities related to the studies under the approval of the IRB.

3. RESPONSIBILITY

All IRB administrative staff, committee members, member secretary and chairperson shall be responsible to conduct of activities with IRB to complete a written communication record for telephone or interpersonal discussions related to past, present and/or future studies and/or processes involving the IRB.

4. FLOW CHART

No.	Activity	Responsibility
1	Communication recording mechanism ↓	IRB secretariat / members / Chairperson
2	Contents of a written record ↓	IRB secretariat / members / Chairperson
3	Distribution of the record	IRB secretariat / members / Chairperson

5. DETAILED INSTRUCTIONS

5.1. Communication recording mechanism

5.1.1. Individuals may utilize different communication recording mechanisms that may be handwritten, typed or computer-generated.

5.2. Contents of a written record

5.2.1. The record shall contain, but is not limited to, the following information:

- 5.2.1.1. Date of communication
- 5.2.1.2. Study information, i.e., sponsor, protocol number, investigator, etc.
- 5.2.1.3. Name of person contacted
- 5.2.1.4. Contact address, telephone number, and e-mail
- 5.2.1.5. Summary of the communication made
- 5.2.1.6. Notation of any follow-up necessary
- 5.2.1.7. Signature of individual completing record

5.3. Distribution of the record

5.3.1. Upon completion of the records, the individual distributes copies to:

- 5.3.1.1. The study file
- 5.3.1.2. Others, as appropriate
- 5.3.1.3. Secretariat or administrative staff for filing

6. ANNEX

Annex 1 AF/01-024/01 Communication Record Form

ANNEX 1
AF/01-024/01

Communication Record Form

Date:				
Means of Contact	<input type="checkbox"/> Telephone	<input type="checkbox"/> Fax	<input type="checkbox"/> e-mail	<input type="checkbox"/> In Person
Person contacted:	<input type="checkbox"/> Reviewer	<input type="checkbox"/> IRB/REC member	<input type="checkbox"/> Media	
	<input type="checkbox"/> Chairperson	<input type="checkbox"/> Secretariat	<input type="checkbox"/> Regulatory	
	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Investigator	<input type="checkbox"/> Others (specify)	
	<input type="checkbox"/> Subject	<input type="checkbox"/> Institute	
Name:				
Telephone No.		Fax No.		
e-mail				
Protocol No.				
Title :				
Communication Issues / Reason for making contact:				
Follow-up Action :	<input type="checkbox"/> Return call	<input type="checkbox"/> will call again	<input type="checkbox"/> None	
	<input type="checkbox"/> See notes	<input type="checkbox"/> Circulation	<input type="checkbox"/> Confidential	
Summary of Communication:				
Recorded by:				