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1. Purpose

The purpose of this SOP is to ensure proper completion, distribution and filing of written communication and other study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies (FMHACA, National Research Ethics Review Board, etc.).

2. Scope

This SOP applies to all communication activities related to the studies under the approval of the EPHI-IRB.

3. Responsibility

It is the responsibility of all IRB administrative staff, Board members, secretariat and chairperson conducting activities with EPHI-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	Hand written, typed or computer-generated recording. ↓	IRB Administrative Staff/Secretariat / Members / Chairperson
2	Recording all written contents/information ↓	IRB Secretariat / Chairperson
3	Distribution of the record	IRB Secretariat / Chairperson


5. Detailed instruction

5.1. Communication recording mechanism

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

5.2. Contents of a written record

- The record should contain, but is not limited to, the following information:

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

5.3. Distribution of the record

- Upon completion of the records, the individual distributes copies to:
 - The study file
 - Others, as appropriate
 - Secretariat or administrative staff for filing

6. Glossary


Communication: Means of sending or receiving written communication and other study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies (FMHACA, National research ethics review board, etc.).

Records A piece of evidence about study, protocol, investigators, sponsors, volunteer subjects, institutes.

7. Reference

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

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Annex 1: Communication Record Form
(EPHI-IRB AF 01-024/02.0)

		Date:		
Means of Contact	<input type="checkbox"/> Telephone	<input type="checkbox"/> Fax	<input type="checkbox"/> e-mail	<input type="checkbox"/> In Person
Status of Contact	<input type="checkbox"/> Incoming Call <input type="checkbox"/> Outgoing Call			
Person contacted:	<input type="checkbox"/> Reviewer	<input type="checkbox"/> IRB Member		
	<input type="checkbox"/> Chairperson	<input type="checkbox"/> Secretariat		
	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Investigator	<input type="checkbox"/> Media	
	<input type="checkbox"/> Subject	<input type="checkbox"/> Institute	<input type="checkbox"/> Regulatory	
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:				