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6.2 Communicating IRB Decisions/ Incoming/ Outgoing Communications

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1. Purpose

The purpose of this SOP is to ensure proper completion, distribution and filing of all verbal and written communication as well as other study-related or process-related information done by investigators, sponsors, volunteer subjects, institution and/or relevant government agencies.



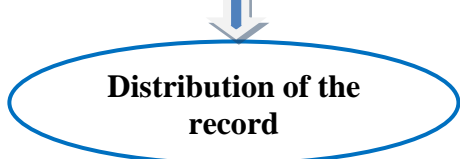
2. Scope

This SOP applies to all IRB decisions/incoming and outgoing communications related to the study approved by the CHH IRB.

3. Responsibility

It is the responsibility of the Chair and the Board members as well as the secretariat to complete a written communication record for telephone or interpersonal discussions related to the past, present and/or future studies and/or processes involving the IRB.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	 <p align="center">Recording of incoming and outgoing communications</p>	CHH IRB secretariat / members / Chairperson
II	 <p align="center">Completion of written records</p>	CHH IRB secretariat / members / Chairperson
III	 <p align="center">Distribution of the record</p>	CHH IRB secretariat / members / Chairperson

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5. Detailed Instruction

5.1 Recording of incoming and outgoing communications

- Individuals may utilize different mechanisms to record communications which may be handwritten, typewritten or computer-generated.

5.2 Completion of written records


- The record should contain, but is not limited to, the following information:
 - Date of communication
 - Study information, i.e., sponsor, protocol number, investigator, etc.
 - Name of person contacted
 - Contact address, telephone number, e-mail, fax, in person
 - Summary of the communications made
 - Notation of any follow-up if necessary
 - Signature of the individual responsible for the recording of the communication

5.3 Distribution of the record

- Upon completion of the records, the individual distributes copies to:
 - The study file
 - Incoming and outgoing communication file
 - Secretariat or administrative staff for filing

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6. ANNEX

 <p>CHONG HUA HOSPITAL Healing with Passion. Caring with Compassion.</p>	<p>COMMUNICATION RECORD FORM</p> <p>Form HRP-IRB-029</p>
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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"/> In coming call <input type="checkbox"/> Outgoing call
Person contacted:	<input type="checkbox"/> Reviewer <input type="checkbox"/> CHH 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
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:	

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7. Reference

- ❖ World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- ❖ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- ❖ National Ethical Guidelines for Health Research 2011 PNHRs