
	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)</b>	<b>SOP /023/2020/01.4</b> <b>Effective date:</b> <b>2 January 2020</b>
	<b><u>Title:</u></b> <b>023. Communication Records</b>	<b>Page 1 of 5</b>

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## **1. Purpose**

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

## **2. Scope**

This SOP applies to all communicating activities related to the studies under the approval of the EC

## **3. Responsibility**

It is the responsibility of all MRIN EC administrative staff, Board members, secretariat and chairperson conducting activities with EC MRIN 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**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
1	Communication recording mechanism ↓	MRIN EC Secretariat / members / Chairperson
2	Contents of a written record ↓	
3	Distribution of the record	MRIN EC Secretariat / members / Chairperson

## **5. Detailed instruction**

### **5.1 Communication recording mechanism**

- Individuals may utilize different communication recording mechanisms that may be typed or computer-generated or email

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## 5.2 Contents of a written and Verbal record

- The record should contain, but is not limited to, the following information:
  - Date of communication
  - Study information, i.e., protocol number, investigator, ethical approval period, etc.
  - Name of person contacted, email address
  - Summary of the communication made
  - Notation of any follow-up necessary

## 5.3 Distribution of the record

- Upon completion of the records, the individual distributes copies to:
  - The study file
  - Will inform to the members during the Board meeting
  - Secretariat or administrative staff for filing

## 6. Glossary

Communication Record	Verbal and written communication related to the information using electronic mails, social media (Whatsapp, Messenger)
Written Communication	Involve any type of interaction that make used of the written word involving more than one person
Verbal Communication	Verbal communication describe any type of interaction between individuals which makes use of word and involves speaking and listening, example business meeting, personal discussion, presentation, teleconference, video conference, interview etc


## 7. Annex

Annex 1      AF/01-023/2020/01.4      Document History

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## **8. Reference**

- Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, 2000, Geneva.
- Surveying and Evaluating Ethical Review Practices, World Health Organization, 2002, Geneva.
- International Conference on Harmonisation (ICH) Harmonised Tripartite : Guideline for Good Clinical Practice E6(R1), Current Step 4 version dated 10 June 1996, November 2005, November 2016
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011, World Health Organization,
- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- SIDCER Self-Assessment Tool, <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.

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**Annex 1**  
Form AF/01-023/2020/01.4

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	<b>Final version</b>
Ivet, Lia, Mona	01.1	11 October 2014	<ol style="list-style-type: none"> <li>1. Synchronize the topic number and SOP number</li> <li>2. Format Document History : Author, Version, Date and Description of the main change</li> <li>3. Section 5.1. Communication recording mechanism : delete handwritten</li> </ol>
Magdarina D. Agtini, Monalisa	01.2	1 April 2017	<ol style="list-style-type: none"> <li>1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header</li> <li>2. Item 1 (Purpose): Delete the word "Investigator"</li> </ol>
Monalisa	01.3	2 January 2019	<ol style="list-style-type: none"> <li>1. Item 5.1 : to add communication recording mechanism using email and delete signature of individual completing record, telephone number, contact address</li> <li>2. Annex 1 : Delete</li> <li>3. Annex 2 becomes Annex 1</li> </ol>
IS, GE, MW,LSH	01.4	2 January 2020	<ol style="list-style-type: none"> <li>1. 5.2, Title : to include " Verbal" record</li> <li>2. Add Glossary for communication record, written communication and verbal communication</li> </ol>