Table of Contents

1. Purpose

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the ethics committee of MRIN
The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics committee are conducted in accordance with the WHO Operating Guidelines for Ethical Review Committee That Review Biomedical Research, National Guideline for Ethics Committees and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP)

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committees of MRIN involving human subjects.

3. Responsibility

It is the responsibility of the secretary of ethics committee to appoint the SOP Team. The SOP Team consists of all MRIN current EC members to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the institute. the SOP Team consist of all current EC Members.

Secretariat of MRIN EC:

- ☐ Co-ordinates activities of writing, reviewing, distributing and amending SOPs
- ☐ Maintains on file all current SOPs and the list of SOP
- ☐ Maintains an up-to-date distribution list for each SOP distributed
- ☐ Distributes the SOPs with a receipt to all users
- ☐ Ensures all ethics committee members and involved administrative staff have access to the SOPs
- ☐ Ensures the ethics committee members and involved staff are working according to current version of SOPs

SOP team:

- ☐ Proposes required SOPs
- ☐ Selects the format and coding system
- ☐ Drafts the SOP in consultation with ethics committee members and involved administrative staff
- ☐ Assesses the request(s) for SOP revision in consultation with the secretariat and Chairperson

Chairperson of the ethics committee:

- ☐ Reviews and approves the SOPs
- ☐ Signs and dates when receives the approved SOPs

Ethics committee members and involved administrative staff:

- ☐ Sign and date when they receive the approved SOPs
- ☐ Maintain a file of all SOPs received
- ☐ Return all out-of-date SOPs to SOP Administrator

4. Flow Chart

No.	Activity	Responsibility
1	Appoint the SOP Team	Secretary
	↓	
2	List all relevant SOPs	SOP Team
	↓	
3	Design a format and layout	SOP Team
	↓	
4	Write and approve a new/revised SOP	SOP Team and Chair person
	↓	
5	Implement, distribute and file all SOPs	Secretariat
	↓	

6	Review and request for a revision of existing SOPs	SOP Team / MRIN EC Members/ Administrative staff/Chair person
	↓	
7	Manage and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Appoint the SOP Team

- ☐ The SOP Team consists of all current EC Members.

5.2. List all relevant SOPs

- ☐ Write down step by step all IEC/IRB procedures.
- ☐ Organize, divide and name each process.
- ☐ Make a list of SOPs with coding reference (Annex 1: AF/01-001/2020/01.3)

5.3. Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YYYY/ZZ.W will be assigned to each SOP item by Secretariat. XXX is a three-digit number assigned specifically to the SOP and Title Number. YYYY is the year of the SOP released. ZZ.W is a number identifying the version of the SOP and the revision number. ZZ identifies the version number and should be started from 01. W is a one digit number identifying the revision number of SOP.

For example, SOP/001/2020/01.3 is the SOP number 001 version 01 with two minor revision i.e. 01.3 in year 2020

Each annex will be given unique code number with the format AF/BB-XXX/YYYY./ZZ.W. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/2020/01.3 means Annex Form number one of the SOP/001/2020/01.3.

Each SOP will be prepared according to the standard template. Please refer to Annex 2 –AF/02-001/2020/01.3

5.4. Write and approve SOP

If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 3 – AF/03-001/2020/01.3).

When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team.
The draft SOP will be discussed with ethics committee members and all relevant administrative staff. The SOP should be agreed upon by the people involved in that particular task. The final version will be passed to the Chair person for review and approval. Chairperson of the Ethics Committee approves and signs the letter denoting the implementation of the SOP(s). The Sop(s) are acknowledged by the Chairman of the MRIN Institution

5.5. Implement, distribute and file all SOPs

- ☐ Members will receive training on revised SOP.
- ☐ The approved SOPs will be implemented from the effective date.
- ☐ The approved SOPs will be distributed to the EC members and the relevant staff by the Secretariat according to the distribution list. (Annex 4 – AF/04-001/2020/01.3). When revised version is distributed, the old version will be retrieved and destroyed.
- ☐ One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the ethics committee and keep the file in the Ethics Committees office.

5.6. Review and request for a revision of an existing SOP

- ☐ Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex 5 – AF/ 05-001/2020/01.3) to make a request.
- ☐ If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of the decision.
- ☐ Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.4).
- ☐ The Secretariat is expected to review the SOPs at least every *2* years and record the dates of review on the SOP Master file.

5.7. Manage and archive superseded SOPs

- ☐ Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the Secretariat**.**

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
MRIN EC Members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., MRIN EC membership). These boards are constituted in accordance with the EC

membership requirements set forth in ICH GCP.

SOP Team	A selected committee of the institute members and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.
Master SOP files	An official collection of the institute standard operating procedures (SOP) accessible to all staff, IEC/IRB members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

7. Annex

Annex 1	AF/01-001/2020/01.3	List of MRIN EC SOPs
Annex 2	AF/02-001/2020/01.3	Standard Operating Procedures Template
Annex 3	AF/03-001/2020/01.3	Document History
Annex 4	AF/04-001/2020/01.3	Log of SOP Recipients
Annex 5	AF/05-001/2020/01.3	Request for Revision of an SOP
Annex 6	AF/06/001/2020/01.3	Document History

8. References

- ☐ 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
- ☐ SIDCER Self-Assessment Tool, http://www.fercap-sidcer.org/selftool.php, accessed January 2013.

Annex 1
Form AF/01-001/2020/01.3

List of SOPs

Topic No.	Topics/ Standard Operating Procedures (SOPs)
	Glossary and Definition of Terms
	Preparing Standard Operating Procedures (SOPs) and Guidelines for Ethics Committees
1	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees
2	Preparation of Guidelines for Human Subjects
	Constituting an Ethics Committee
3	Constituting an IEC/IRB
4	Confidentiality / Conflict of Interest Agreements
5	Training Personnel and IEC/IRB Members
6	Selection of Independent Consultants
	Initial Review Procedures
7	Management of Protocol Submissions
8	Use of Study Assessment Forms
9	Expedited Review

10	Initial Review of Submitted Protocols
11	Review of New Medical Devices Studies
	Protocol Amendments, Continuing Review, and End of Study
12	Review of Resubmitted Protocols
13	Review of Protocol Amendments
14	Continuing Review of Study Protocols
15	Review of Final Reports
	Monitoring Protocol Implementation
16	Non-Compliance/Violation Intervention
17	Response to Participants' Requests
18	Management of Study Termination
	Monitoring and Evaluation of Adverse Events
19	Review of Serious Adverse Events (SAE) Reports
	Site Monitoring
20	Site Monitoring Visit
	Preparation of Review Meeting Agenda and Communication Records
21	Agenda Preparation, Meeting Procedures and Minutes
22	Emergency Meeting

23	Communication Records
	Managing Study Files
24	Maintenance of Active Study Files
25	Archive and Retrieval of Documents
26	Maintaining Confidentiality of IEC/IRB's Documents
	Evaluating an IEC/IRB
27	Audit and Inspection of the IEC/IRB

Annex 2
Form AF/02-001/2020/01.3

Standard Operating Procedures Template

	Name of Insitution	SOP/XX/ZZZZ/YY.Y Effective date: ? Page ? of ?
	Title: **SOP X.X and SOP Title which is self explanatory and is easily understood**	

Table of CONTENTS

Annex:

Annex 2
Form AF 02-001/2020/01.3

Main Text:

1. **Purpose** - *summarizes and explains the objectives of the procedure.*

2. **Scope** – *states the range of activities that the SOP applies to.*

3. **Responsibility** – *refers to person(s) assigned to perform the activities involved in the SOP*

4. **Flow chart** – *simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

5. **Detailed instructions** – *describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*

6. **Glossary** – *clarifies uncommon or ambiguous words or phases by explanation.*

7. **Reference** – *lists sources of the information given in the SOP.*

8. **ANNEX** - *documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.*

Annex 3
Form AF/03-001/2020/01.3

Document History

The SOP History should be produced as the output of the final version which is the version after the approval by the Chairperson (01.0)

Author –	Version	Date	Describe the main change
name	01.0	*dd-Mmm-yy*	final version
name	01.1	*dd-Mmm-yy*	Minor changes
name	02.0	*dd-Mmm-yy*	Major changes
name	02.0	*dd-Mmm-yy*	No change (routine review)

Annex 4
Form AF/04-001/2020/01.3

Log of SOP Recipients

No.	Name of Recipients	SOP#	No. of Copies	Signature	Date
1	*Chairperson*	*SOP/001/2014/01.1* *SOP/002/2014/01.1* *SOP/003/2014/01.1*			
2	*Dr. XXXX*	*SOP/001/2014/01.1* *SOP/002/2014/01.1* *SOP/003/2014/01.1*			

Annex 5
Form AF/ 05-001/2020/01.3

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP/001/2014/01.0		
Title:		
Details of problems or deficiency in the SOP:		
Identified by:	Date (D/M/Y):	
Discussed with:		
SOP revision required:	☐ Yes	☐ No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP re-finalized:		
Date SOP approved:		
Date SOP becomes effective:		

Annex 6

Form AF/06-001/2020/01.3

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	**Final version**
Ivet, Lia, Mona	01.1	11 October 2014	1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Irawan Yusuf, Lia, Budhianto S, Monalisa	01.2	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.4. : To add sentence Members will receive training on revised SOP.
IS,LSH,MW, GE	01.3	2 January 2020	1. 5.3 : Delete the word of "three digit" 2. 5.3 : Delete the sentences of "SOP with minor changes in the SOP" 3. 5.3 : Add sentence "and the revision number" 4. 5.4 : Add the statement of "Chairperson of the Ethics Committee approves and signs the letter denoting the implementation of the SOP(s). The Sop(s) are acknowledged by the Chairman of the MRIN Institution" 5. 5.4 : move the statement of " Members will receive training on revised SOP" to the 5.5 6. Add 5.5,Box 1 : Members will receive training on revised SOP 7. 5.5, Box 1 – 3 becomes Box 2 -4 8. Annex : Delete SOP Code

			9. References : • Add ICH GCP November 2016 • Delete link WHO • Delete FERCAP SOP 10. Table of Contents : No.7 becomes No.8, No.8 becomes No.7