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1. Purpose

The purpose of SOP is to provide instructions on the review and follow-up of the Final Reports for any study approved by the MRIN EC.

2. Scope

This SOP applies to review and follow-up of the Final Reports which is an obligatory review of each investigator's activities presented as a written report of studies completed to the MRIN EC

In addition to the study report form (AF/01-015/2020/01.5) Investigator may include any other mechanism (letter format, form provided by the Sponsor, publications, etc.)

3. Responsibility

It is the responsibility of the MRIN EC Secretariat to check the report for completeness before making copies for the Board meeting, communicate and archive the decision of the Board. The Board Meeting is responsible to review, follow up and approve of the final report. Review of the Final Report should be done by the Primary Reviewer

4. Flow chart

No.	Activity	Responsibility
1	Activities before a Board meeting	EC Secretariat
	↓	
2	Activities during the Board meeting	EC Secretariat / Members / Chairperson/Vice Chairperson
	↓	
3	Activities after the Board meeting	EC Secretariat

5. Detailed instructions

5.1 Activities Before each Board meeting

- ☐ See SOP/007/2020/01.4 (Management of Protocol Submission) for receiving and checking the report packages.

- ☐ The Secretary Vice Chairperson/Chairperson reviews the submitted report and decides whether full board meeting is needed.
- ☐ The Secretariat makes sufficient number of copies

5.2 Activities During the Board meeting

- ☐ Each Board member reviews a copy of the Final Report.
- ☐ The Chairperson/Vice Chairperson/Secretary or designee entertains any discussion of the study.
- ☐ If appropriate to the discussions, a MRIN EC member may call for consensus on whether to request further information or to take other action with the Principal Investigator.
- ☐ Chairperson summarizes what action should be taken. (Accepted or Accepted with remarks)

5.3 Activities After the Board meeting

- ☐ Notify the investigator of the decision.
- ☐ Accept and file the Final Report, if no action is taken.
- ☐ Note the decision in the meeting minutes
- ☐ Consider the study as closed.
- ☐ Get a copy of the final report signed by the Chairperson/Vice Chairperson Secretary.
- ☐ Archive the entire study protocol and the final report.

6. Glossary

Primary Reviewer	Member designated by the Chairperson/Vice Chairperson/Secretary as a reviewer

7. Annex

Annex 1 AF/01-015/2020/01.5Study Report Form
Annex 2 AF/02-015/2020/01.5 Document History

8. References

- ☐ Peraturan Pemerintah Republik Indonesia Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan, http://www.litbang.depkes.go.id /unduh_pp
- ☐ 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
- ☐ Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- ☐ 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.
- ☐ Associated SOP/007/2020/01.4.
- ☐ Standard Operating Procedures UP Manila,2019

Annex 1
Form AF/01-015/2020/01.5

Study Report Form

Protocol No.:		**Submission date :**
Protocol Title :		
Principal Investigator:		
PARENT PROTOCOL APPROVAL PERIOD DATE:		
Phone number:		**E-mail address :**
Sponsor's Name		
Address:		
Phone :		**E-mail :**
Study site(s):		
Total Number of study participants :		**No. of Study Arms:**
Summary of Recruitments		
Accrual ceiling set by EC :		
New participants accrued since the last review :		
Total number of participants accrued since protocol began :		
Number of participants who are lost to follow up :		
Number of participants who experienced SAEs/SUSARs :		
▪ Number of participants withdrawn from the study :		
Number of participants who received the test articles:		

Study materials:	
Treatment form:	
Study dose(s):	
Duration of the study	
Objectives:	
Results: (Use extra blank paper, if more space is required.)	

Summary of previous protocol amendment (if any)

Approval amendment nomor.	Short description of the amendment	Approved date

Summary of participants complaints or grievances documented regarding conduct of study :

Summary of benefits to participants :

Summary indemnifications (compensation) of study related injury (if applicable) :

If terminated early, specify reason for termination :

Progress reports submitted (with dates of approval) :

Duration of the study :

Informed consent from used (with version no/date) and attach most recent

015. Review of Final Report

version :
Study objectives and summary of results :
Adverse /Unanticipated Events : ▪ Did you experience any unanticipated adverse events, complication or incidence ☐ Yes ☐ No If yes, describe the event and how it was handled ▪ **Summary of onsite SAEs reported**
▪ Did you receive any complaints about the research ? ☐ Yes ☐ No If yes, describe the complaint and how it was handled
Data Storage
1. Where are your project files being stored ?
2. Have you verified the status of all project files and confirmed they are stored in a safe and secure location ? Data must be kept for at least 3 years after project is completed ☐ Yes ☐ No If No, Please explain :

Signature of PI :	Date:

☐ **Accepted**

☐ **Accepted with remarks . If accepted with remarks, please state the remarks :**
……
……
……

SIGNATURES:

_____ Date:……
Protocol Reviewer

ACCEPTED:

_____ Date: ……..
Chairperson/Vice Chairperson, MRIN EC

COMPLETION:

_____ Date:……
Secretary, MRIN EC

Annex 2
Form AF/02-015/2020/01.5

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 3. Section 5.1. : Post approval documents should be reviewed by the primary reviewers 4. Annex 1 : addition of section for reviewer comments and EC decision
Ivet, Lia, Mona	01.2	15 November 2014	1. Section 5.6.1 : "Post Approval Documents" replace with "Final Report" 2. "Review of the Final Report should be done by the Primary Reviewer" under Section 3
George Mathew, Dondin Sajuthi	01.3	1 April 2017	1. Delete Komisi Etik Penelitian Kesehatan (KEPK) 2. Annex 1: To add comment of reviewer: Accepted and accepted with remarks 3. Annex 1: To replace "approval" to "accepted" for the decision of Chair 4. Annex 1: To replace the word "Assigned No:" to "Submission Date" 5. Annex 1: To add "Ethical Approval Period" as a new line
Mona	01.4	2 January 2019	1. Item 4.2. 5.2 , 5.3 and 6 : To add Vice Chairperson 2. Annex 1 ; Include Summary of previous protocol amendment. AE and Data Storage

MW,IS,LSH, GE	01.5	2 January 2020	1. Scope : replace “although” with “In addtion to the ....mechanism” 2. 5.1 – 5.3 : add statement of the “activities” 3. 5.2. box 4 : replace “condition” with “accepted and accepted with remark” 4. Glosarry : Replace “Designee Reviewers“ with “Primary Reviewers” 5. Annex Study Report Form : to add Summary Recruitments 6. References : • Delete link WHO • Delete FERCAP SOP • Add ICH Nov 2016