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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

<table>
<thead>
<tr>
<th>No.</th>
<th>Activity</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Activities before a Board meeting ↓</td>
<td>EC Secretariat</td>
</tr>
<tr>
<td>2</td>
<td>Activities during the Board meeting ↓</td>
<td>EC Secretariat / Members / Chairperson/Vice Chairperson</td>
</tr>
<tr>
<td>3</td>
<td>Activities after the Board meeting</td>
<td>EC Secretariat</td>
</tr>
</tbody>
</table>

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.
Title: 015. Review of Final Report

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

8. References
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- Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- Associated SOP/007/2020/01.4.
- Standard Operating Procedures UP Manila, 2019
# 015. Review of Final Report

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

## Study Report Form

<table>
<thead>
<tr>
<th>Protocol No.</th>
<th>Submission date</th>
</tr>
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<tbody>
<tr>
<td>Protocol Title</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Principal Investigator</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>PARENT PROTOCOL APPROVAL PERIOD DATE</th>
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<table>
<thead>
<tr>
<th>Phone number</th>
<th>E-mail address</th>
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<table>
<thead>
<tr>
<th>Sponsor’s Name</th>
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</table>

<table>
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<table>
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<tr>
<th>Phone</th>
<th>E-mail</th>
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</table>

<table>
<thead>
<tr>
<th>Study site(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total Number of study participants</th>
<th>No. of Study Arms</th>
</tr>
</thead>
</table>

## Summary of Recruitsments

<table>
<thead>
<tr>
<th>Accrual ceiling set by EC</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>New participants accrued since the last review</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total number of participants accrued since protocol began</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Number of participants who are lost to follow up</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Number of participants who experienced SAEs/SUSARs</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Number of participants withdrawn from the study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of participants who received the test articles</th>
</tr>
</thead>
</table>
Title:

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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)

<table>
<thead>
<tr>
<th>Approval amendment nomor.</th>
<th>Short description of the amendment</th>
<th>Approved date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
### 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:

<table>
<thead>
<tr>
<th>Date:</th>
<th>Signature of PI:</th>
</tr>
</thead>
</table>
015. Review of Final Report

☐ 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
# 015. Review of Final Report

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

## Document History

<table>
<thead>
<tr>
<th>Author</th>
<th>Version</th>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>EC Members</td>
<td>01.0</td>
<td>2 January 2013</td>
<td>Final version</td>
</tr>
</tbody>
</table>
| 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 |
Title: 015. Review of Final Report

<table>
<thead>
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<th>MW,IS,LSH, GE</th>
<th>01.5</th>
<th>2 January 2020</th>
</tr>
</thead>
</table>

1. Scope: replace “although” with “In addition 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”
5. Annex Study Report Form: to add Summary Recruiments
6. References:
   - Delete link WHO
   - Delete FERCAP SOP
   - Add ICH Nov 2016