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1. Purpose

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance to GCP/GLP

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the EC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility

It is the responsibility of the MRIN EC to perform or designate some qualified members to perform on its behalf on-site inspection of the research projects it has approved.

The EC members in consultation with the Chairperson/ Secretary may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	MRIN EC members and Chairperson
	↓	
2	Procedures before the visit	MRIN IEC members
	↓	
3	Procedures during the visit	MRIN EC members
	↓	
4	Procedures after the visit	MRIN EC members
	↓	
5	Present the findings to the Full Board	MRIN EC members

5. Detailed instructions

5.1 Selection of study sites

- ☐ Review periodically the database files of the submitted/approved study protocols.
- ☐ Select study sites needed to be monitored based on the following criteria:
  - ☐ The nature of the study being conducted (i.e. high risk studies)
  - ☐ Frequent non-submission or failure to submit continuing review requirements
  - ☐ Reports of major protocol noncompliance
  - ☐ Significant number of serious adverse events
  - ☐ Reports of complaints from study participants
  - ☐ Site visits may be conducted upon recommendation of the Panel

5.2 Procedures Before the visit

The MRIN EC designated **members** will

- ☐ Contact the PI to notify them that they will be visiting them, **two weeks in advance**. At that time, the monitoring team and the PI will coordinate a time for the site evaluation visit.
- ☐ Make the appropriate travel arrangements.
- ☐ Review **the protocol files** for the study and site,
- ☐ Make appropriate notes, or
- ☐ Copy some parts of the files for comparison with the site files.

5.3 Procedures During the visit

- ☐ Get a checklist AF/01-020/2020/01.4 (ANNEX 1).
- ☐ The MRIN EC **designated members** will
  - ☐ Review the informed consent document to make sure that the site is using the most recent version,
  - ☐ Review randomly the subject files to ensure that subjects are signing the correct informed consent,
  - ☐ Observe the informed consent process, if possibl**e,**
  - ☐ Observe the welfare of the study subjects
  - ☐ Observe laboratory, animals and other facilities necessary for the study at the site.
  - ☐ Review the MRIN EC files for the study to ensure that documentation is filed appropriately **including adverse event**
  - ☐ Collect views of the study participants.
  - ☐ Debrief the visit report/comments.
  - ☐ Give feed back to the PI

5.4 Procedures After the visit

The MRIN EC **designated members** will:

- ☐ Write a report/comment (use the form AF/01-020/2020/01.4, see ANNEX 1) within 7 working days describing the findings during the audit
- ☐ Forward a copy of the site visit to the 'site monitoring' file for Full Board review.
- ☐ Place the report in the correct site files.

5.5 Present the findings to the Full Board

- ☐ Consult with the EC Secretary.
- ☐ Schedule the presentation in the meeting agenda.
- ☐ Present the results of on-site inspections to the Full Board.
- ☐ Send a copy of the report of the full board meeting to the PI for their action

6. Glossary

MRIN EC designated	MRIN EC may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to EC.
Monitoring visit	An action that MRIN EC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. Annex

Annex 1	AF/01-020/2020/01.4 Checklist of a Monitoring Visit
Annex 2	AF/02-020/2020/01.4 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.

Annex 1
Form AF/01-020/2020/01.4

Checklist of a Monitoring Visit

Protocol No.:	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor:	Address:
Reason for Site Visit :	Persons Interviewed :
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are the test articles properly kept and maintained ☐ Yes ☐ No	Comment:
Are informed consent forms complete ☐ Yes ☐ No	Comment:
Are copies of the approved versions of the protocol documents kept in the site ? ☐ Yes ☐ No	Comment:
Are files of all communication with EC found in the site? ☐ Yes ☐ No	Comment:
Does the site keep copies of all communication with the EC in the site ☐ Yes ☐ No	Comment:
Are copies of adverse event reports kept? ☐ Yes ☐ No	Comment:
Are Investigator functions properly delegated to qualified research personnel?	Comment:

☐ Yes ☐ No		
Is there appropriate documentation of qualifications of personnel ? ☐ Yes ☐ No	Comment:	
Are the copies of protocol deviation / violation reports kept in the site? ☐ Yes ☐ No	Comment:	
Is there evidence of appropriate corrective action take as recommend by the EC ? ☐ Yes ☐ No	Comment:	
Are Informed Consents recent? ☐ Yes ☐ No	Comment:	
Any adverse events found? ☐ Yes ☐ No	Comment:	
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:	
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:	
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:	
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:	
Any remaining tasks or results of visit? ☐ Yes ☐ No	Give details:	
Duration of visit: …….hours	Starting from:	Finish:
Name of MRIN EC member/ representatives and companion:		
Completed by:		Date:

Annex 2

Form AF/02-020/2020/01.4

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
Lia Siti Halimah, Dondin Sajuthi, Magdarina D. Agtini, Sintak Gunawan	01.2	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.1 : Delete the word "frequently" and replace with "failure" 3. Annex 1: a. Replace the word "outstanding tasks" with "remaining tasks" b. To add two new lines: "How well are experimental animals taken cared? and "How well animal welfare is implemented?"
LSH, MW, IS	01.3	2 January 2019	4. Annex 1 : Exclude questionnaire related to animal study
LSH,MW,GE, IS	01.4	2 January 2020	1. Detailed Instruiction : Judul samakan dengan flow chart 5.3 , 5.4, 5.5. 2. Annex : add content 3. References : • Delete link WHO • Delete FERCAP SOP • Add ICH Nov 2016