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1. Purpose

To provide instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national / international guidelines for the conduct of human and animal research, including those who fail to respond to the MRIN EC's requests.

2. Scope

This SOP applies to all MRIN EC approved research protocols involving human and animal subjects.

3. Responsibility

The responsibility of the Board is to identify, decide the deviation and take appropriate action. The designated member of the MRIN EC members is responsible for collecting and recording the non-compliance list (AF/01-016/2022/01.5). Protocol Deviation Report must be reviewed by the Primary Reviewer

4. Flow chart

No.	Activity	Responsibility
1	Noting protocol deviation / non-compliance / violation.	EC members and Chairperson
	↓	
2	Board discussion and decision	EC members and Chairperson
	↓	
3	Notify the investigator	EC Secretariat,
	↓	
4	Keep records and follow up	EC Secretariat

5. Detailed instructions

5.1 Noting Protocol Deviation/ Non-Compliance/ Violation

EC members may identify protocol deviation/violation from progress report or site monitoring

- ☐ Ensure that the issues as well as the details of deviation /non-compliance/violation involving research investigators are included in the agenda of the MRIN EC meeting.
- ☐ Maintain a file that identifies investigators who are found to be non-compliance with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the MRIN EC's request for information/action.

5.2 The MRIN EC's Decision

- ☐ The Board should receive protocol deviation and violation report before taking action
- ☐ The Board may suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.
- ☐ The chairperson notifies the investigator of the MRIN EC's action in writing, when the Board
  - ☐ Suspend or terminate approval
  - ☐ Corrective action required
  - ☐ Site visit needed
  - ☐ refuse subsequent applications from the investigators cited

5.3 Notify the investigator

- ☐ The MRIN EC Secretariat members record the MRIN EC's decision.
- ☐ Draft and type a notification letter.
- ☐ Get the Chairperson to sign and date the letter.
- ☐ Make copies of the notification letter.
- ☐ Send the original copy of the notification to the investigator.
- ☐ Send a copy of the noftification to the relevant national authorities and institute
- ☐ Send the third copy to the sponsor or the sponsor's representative of the study

5.4 Keep records and follow up

- ☐ Keep the last copy of the notification letter in the "non-compliance" folder of protocol file.

- ☐ Store the file in the shelf with an appropriate label.
- ☐ Follow up the action after a reasonable time.

6. Annex

Annex 1	AF/01-016/2022/01.5	Deviation/Non-Compliance/Violation Record
Annex 2	AF/02-016/2022/01.5	Document History

7. 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.
- ☐ Standard Operating Procedure Ethics Committee of University of Philippine Manila. 2019
- ☐ Declaration Helsinki, 2013
- ☐ Council for International Organizations of Medical Sciences (CIOMS), 2016
- ☐ SOP UPM Manila,Nov 2021

Annex 1
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Deviation / Non-Compliance / Violation Report

Protocol Number :			
Study Title:			
Investigator			Contact No.:
Institution:			Contact No.:
Sponsor:			Contact No.:
1	Description of Reported Deviation / Violation *(identify who committed the deviation and described the reported deviation)*		
	1.1	☐ Patient : ……..	
	1.2	☐ Investigator : …….	
	1.3	☐ Sponsor : …….	
2	Nature of Report		
	2.1	☐ Minor Protocol Deviation *(Non systematic protocol non compliance with minor consequences in terms of its effect on the Participant's/subject's rights, safety or welfare or the integrity of study data : includes deviation that are administrative in nature)*	
3	DESCRIPTION OF INVESTIGATOR PREVENTIVE ACTION :		
4	DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION :		

5	SPONSOR ASSESSMENT OF SEVERITY :	
	5.1	☐ MAJOR
	5.2	☐ MINOR
6	DESCRIPTION OF SPONSOR CORRECTIVE ACTION :	
7	DATE OF DEVIATION / VIOLATION : (dd/mm/yyyy)	
8	REPORTED BY :	
9	DATE OF REPORT : (dd/mm/yyyy)	
10	PI Signature :	

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Deviation / Non-Compliance / Violation Assessment

Comments of Primary Reviewer (i.e whether non compliance have potentially serious consequences that could critically affect data integrity or put patients safety at risk) …… ……
Recommended Action :
☐ No Further Action
☐ Request Information : …….(indicate information)
☐ Recommend Further Action : ……. (indicate action)
☐ Pending, if Major Clarifications are required before a decision can be made
Signatures : Protocol Reviewers Date :
APPROVAL: Chairperson, MRIN EC Date: …….. COMPLETION: Secretary, MRIN EC Date: ……..

Annex 3
Form AF/03-016/2022/01.5

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 of reviewer's signature
Ivet, Lia, Mona	01.2	15 November 2014	1. Section 5.1. : Replace "Post Approval Documents" with "Protocol Deviation Report" 2. "Protocol Deviation Report must be reviewed by the Primary Reviewer" under Sec 3 3. Adition of "No further Action" and "Request Information" under Section 5.2.
Budhianto Suhadi, Debbie S. Retnoningrum	01.3	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header
MW,IS,GE,LSH	01.4	2 January 2020	1. 5.1 Replace the statement of "whenever protocol deviation…. Has been observed with "EC members may identify protocol deviation…. Or site monitoring" 2. 5.2. Delete " Requires further information, Needs no further action " and replace with "suspend or

			terminate approval, corrective action required, site visit needed., etc." 3. References : • Delete link WHO • Delete FERCAP SOP • Add ICH Nov 2016 4. Revise Annex
MW,LSH	01.5	02 January 2022	1. Modified Form Annex 1 2. Form consist of two Annexes (Annex 1 & Annex 2) 3. Move "Glossary" into one page 4. Section 7 beome section 6, section 8 become section 7 5. Item 5.2, add box 1 "The Board should receive protocol deviation and violation report before taking action" 6. Annex 1 : change the word of "Application Number" to "Protocol Number" 7. References : Add Declaration Helsinki 2013 & CIOMS 2016