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1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the MRIN EC manages protocol submissions to the MRIN EC

2. Scope

Protocol submissions include:

- ☐ Submission for Initial Review
- ☐ Resubmission of Protocols with Corrections
- ☐ Protocol Amendment
- ☐ Continuing Review of Approved Protocols
- ☐ Protocol Termination
- ☐ Final Report / Study Report
- ☐ Protocol Deviation

3. Responsibility

It is the responsibility of the MRIN EC Secretariat to receive, record, distribute for review and get the package submission, as well as to deliver the review results to the protocol applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	MRIN EC Secretariat
	↓	
2	Check for submission items: ☐ Initial Review Application ☐ Resubmission of Protocols with Corrections ☐ Protocol Amendment ☐ Continuing Review of Approved Protocols ☐ SAE/SUSAR ☐ Protocol Termination ☐ Final Report / Study Report ☐ Protocol Deviation	MRIN EC Secretariat
	↓	
3	Complete the submission process	MRIN EC Secretariat
	↓	

4	Store the received packages	MRIN EC Secretariat

5. Detailed instructions

5.1 Receive submitted packages

5.1.1 Initial Review Application

- ☐ Go to 5.2.

5.1.2 Resubmission of Protocols with Corrections

- ☐ Retrieve the previous receipt form from the Secretariat's records.
- ☐ Go to step 5.2.1.2

5.1.3 Protocol Amendment

- ☐ Retrieve the previous receipt form from the Secretariat's records.
- ☐ Go to step 5.2.1.3

5.1.4 Continuing Review of Approved Protocols

- ☐ Retrieve the previous receipt form from the Secretariat's records.
- ☐ Go to step 5.2.1.4

5.1.5 Protocol Termination

- ☐ Retrieve the previous receipt form from the Secretariat's records.
- ☐ Go to step 5.2.1.5

5.1.6 Final Report / Study Report

- ☐ Retrieve the previous receipt form from the Secretariat's records.
- ☐ Go to step 5.2.1.6

5.2 Check for submission items

5.2.1 Get relevant forms:

5.2.1.1 Initial Review Application

- ☐ Ensure PIs have submitted Final report of the previous studies before submitting new protocol
- ☐ a document receipt form, AF/01-007/2022/01.5 and
- ☐ an application form for initial review (see Annex 1 , Annex 2 and Annex 3 of SOP/010/2022/01.5).
- ☐ Go to step 5.2.2.
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 should be attached).

5.2.1.2 Resubmission of Protocols with corrections

- ☐ a document receipt form (AF/01-007/2022/01.5, and
- ☐ a review form (AF/01-012/2022/01.6) in Annex 2 (SOP/012/2022/01.6)
- ☐ Go to step 5.2
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 should be attached).

5.2.1.3 Protocol Amendments

- ☐ a document receipt form, AF/01-007/2022/01.5, and
- ☐ a re-review report form, AF/01-013/2022/01.7
- ☐ Go to step 5.2.2
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 should be attached).

5.2.1.4 Annual Continuing Reviews of Approved Protocols

- ☐ a document receipt form, AF/01-007/2022/01.5, and
- ☐ a re-review report form, AF/01-014/2022/01.7
- ☐ Go to step 5.2.2
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 should be attached).

5.2.1.5 Protocol Termination

- ☐ a document receipt form, AF/01-007/2022/01.5, and
- ☐ a re-review report form AF/01-018/2022/01.6
- ☐ Go to step 5.2.2
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 should be attached).

5.2.1.6 Final Report

- ☐ a document receipt form, AF/01-007/2022/01.5, and
- ☐ a re-review report form AF/01-015/2022/01.6
- ☐ Go to step 5.2.2
- ☐ For e-submission, go to 5.2.4 (Filled AF/01-010/2022/01.5 or AF/02-010/2022/01.5 and/or AF/03-010/2022/01.5 or should be attached).

5.2.1.7 Protocol Deviation

- ☐ A Document receipt form, AF/01-007/2022/01.5

- ☐ A re-review report form AF/01-016/2022/01.5
- ☐ Go to step 5.2.2
- ☐ For e-submission go to 5.2.4 (filled AF/01-010/2022/01.5 should be attached)

5.2.2 Fill in the forms:

- ☐ Use the form AF/01-007/2022/01.5 and fill up with relevant information submitted by PI (AF/01-010/2022/01.5, and related to submission form)

5.2.3 Verify Contents of Submitted Package

- ☐ Check the applicable documents to ensure that all required forms and materials are contained within the submitted package.
- ☐ Verify contents of the protocol submitted package to include Informed Consent Form
- ☐ Check completeness of necessary information in the protocol submission of the study protocol for inclusion of the followings :
  - ❑ Title of the Protocol
  - ❑ Principal Investigator
  - ❑ Sponsor
  - ❑ Abstract
  - ❑ Type of Protocol (screening, survey, clinical trial and phase)
  - ❑ Objectives
  - ❑ Anticipated Outcome
  - ❑ Inclusion/Exclusion Criteria
  - ❑ Withdrawal or discontinuation Criteria
  - ❑ Modes of Treatment Studied
  - ❑ Methodology (synopsis of study design)
  - ❑ Analysis (methods)
  - ❑ Activity plan / Timeline
  - ❑ IND Number (if applicable)
  - ❑ Schedule and Duration of Treatment
  - ❑ Efficacy or Evaluation Criteria (Response/Outcome)
  - ❑ Safety Parameters Criteria (Toxicity)

☐ Check the submitted **Protocol and Related Documents** for the following contents

Attachment 1. Information for Subject
Attachment 2. Informed Consent Form & Check list
Attachment 3. Memorandum of Understanding between Researcher, Sponsor and Research Institution (For Research Collaboration)
Attachment 4. Ethical Approval from Other Institution (When Available
Attachment 5. Case Report Form/ Incidence Card
Attachment 6. Forms: Questionnaire, Laboratory/Radiology Examination Request, Laboratory/Radiology Examination Results
Attachment 7. Adverse Event Report Form
Attachment 8. Investigator's Brochure (When Necessary)
Attachment 9. Investigational Drugs Request Letter to or Approval from BPOM (New Drugs/Food Trial)
Attachment 10. Result of the Pre-Clinical Study using of Animals (for Phase I and II)
Attachment 11. Budgeting Details and Funding Resources
Attachment 12. Others (e.g. Workflow)

☐ See if changes made to the documents be underlined or highlighted.

5.2.4. Verify electronic documents (where applicable)

☐ Place the electronic computer documents (protocol summary, protocol and protocol-related documents) on the MRIN EC server or the Local Area Network at the time of submission for initial protocol review or protocol amendment packages in the following drive and folder:

Name of drive (D:\Ethics Commitee\protocols\short name of title)

☐ Verify that the electronic version and the contents of the documents.
☐ Print out the protocol documents.
☐ Verify the correctness of the documents.
☐ Check that all pages of the documents have been included and that the submitted protocol and protocol-related documents do not have missing pages.
☐ Certify the printed hard copy in the same manner as the submitted document(s) with the dated signature.

☐ Assign a running number to the received protocols, applying the system of 9 digits. The first four digits indicate the last two digits of the year, followed by number of the month. The next three digits are the running number of the year followed by institution code, 01 for protocol from MRIN, 02 from Faculty of Medicine (FoM)-Universitas Pelita Harapan (UPH), 03 from Siloam Hospitals, 04 from Faculty of Nursing, Universitas Pelita Harapan, 05. Faculty of Science and Technology, Universitas

Pelita Harapan, 06. Others. For example 1306001-01 means the first protocol submitted in June 2013 from MRIN.

- ☐ Assign a running number to the received protocols, applying the system of 10 digits. The first four digits indicate the last two digits of the year, followed by number of the month. The next three digits are the running number of the year followed by institution code, and type of protocols (Clinical and Non Clinical Trial). 01 for protocol from MRIN, 02 from Faculty of Medicine (FoM)-Universitas Pelita Harapan (UPH), 03 from Siloam Hospitals, 04 from Faculty of Nursing, Universitas Pelita Harapan, 05. Department of Biology, Universitas Pelita Harapan, 06. Others. A, for clinical protocol. B,for Non-clinical protocols For example 2201001-01A means the first protocol submitted in January 2022 from MRIN for Clinical Trial
- ☐ Store the electronic document with the submitted documents.
- ☐ Use the assigned running number of the protocol as the labeled name.
- ☐ Identify clearly as the electronic document.

5.2.5 Create a Protocol Submission File

- ☐ Get the "**Protocol Submission"** file.
- ☐ Record the name and the number of the submitted protocol.
- ☐ Record the receiving date and the name of the receiver.

5.3 Complete the submission process

- ☐ Check for completeness of information.
- ☐ Notify the applicants if a package is incomplete.
- ☐ State clearly the items missing in the package.
- ☐ Fill up the related parts and the missing documents.
- ☐ Write the receiving date on the letter and the first page of the documents.
- ☐ Initial the receiver's name on the receiving documents.
- ☐ Make a photocopy of the completed Form AF/01-007/2022/01.5.
- ☐ Return the original copy of the AF/01-007/2022/01.5 to the applicants for their records.
- ☐ Keep the copy of the document receipt form in the Protocol file.
- ☐ Attach an Initial Review Application Form (AF/01-010/2022/01.5) to the Research Protocol packages.
- ☐ Keep the submitted documents with digital signatures in the "Submission" file

5.4 Store the received packages

- ☐ Storage the document packages together appropriately.

- ☐ Store the dated and initial protocol packages on the MRIN EC submission shelf for review in FIFO sequence.

6. Annex

Annex 1 AF/01-007/2022/01.5 Document Receipt Form
Annex 2 AF/02-007/2022/01.5 Document History

7. Reference

- ☐ 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,
- ☐ Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- ☐ Associated SOPs: SOP/008/2022/01.6, SOP/010/2022/01.5 and SOP/011/2022/01.4
- ☐ Declaration Helsinki, 2013
- ☐ Council for International Organizations of Medical Sciences (CIOMS), 2016

Annex 1

Form AF/01-007/2022/01.5

Document Receipt Form

Received number:			
Protocol Number:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments ☐ **SAE/SUSAR** ☐ Continuing Review of Approved Protocols	☐ **Final Report** ☐ Protocol Termination ☐ Deviation / Non-Compliance / Violation Record ☐ Queries, Notifications and Complaints	
Protocol Title:			
Principal Investigator:			
Telephone number:		**Fax :**	
E-mail:		**Preferred Contact**	☐ Phone ☐ Fax ☐ e-mail
Institute:			
Delivery route:	☐ Post ☐ E-submission ☐ in Person		
Documents submitted:	☐ complete ☐ incomplete, will submit on……..		
Documents to be submitted later :	☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others……	Check what documents are received later on. ☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others……	
Other Documents			
Received by:			
Date received:			

Note: *Please bring this receipt with you when contacting the MRIN EC*

Annex 2
Form AF/02-007/2022/01.5

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 5.2.3. : Protocol coding to reflect a better definition of internal (MRIN) and external (UPH and Siloam Hospitals) 4. Annex 1 : Initial Review Submitted Package
Debbie S. Retnoningrum , Yan Nuryanto, Monalisa	01.2	1 April 2017	1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.2.4 : Delete the word "stamp" 3. Item 5.3 box 6: Delete the word "stam[" and change to "write the recieving" 4. Item 5.3 box 10 : ,Delete the sentence "Attach the filled checklist (AF/01-007/2017/01.2) with the copy of the form AF/02-007/2017/01.2 with a staple" 5. Delete Annex 1. Annex 2 became Annex 2, add "Final report" in the Type of Submission and add "other documents" as a new line
Monalisa	01.3	2 January 2019	1. Item 5.2.4. : to change and add institution code 04. Faculty of Nursing, UPH, 05. Department of Biology, UPH, 06. Others 2. Annex 1& Flow chart : to add SAE/SUSAR in the type of submission
IS,LSH,MW,	01.4	2 January 2020	1. 5.2.1.1 , box 2 to include annex 2 & 3 of SOP 010.

GE			2. 5.2.1.1 – 5.2.1.6, box 4 : to include Annex 2 & 3 of SOP 3. 5.2.2,box 1 : replace the word of "give" with " use " 4. 5.2.3 Replace the " Verify contents of the protocol submitted package to include : • 1. Original Application Form for Initial Review….. and Protocol related documents" with " Verify contents of the protocol submitted package to include Informed Consent Form" 5. 5.2.5 : replace the word of " Specific File" with "Submission File" 6. 5.3 box 1 : delete . 5.3 box 2 -12 becomes 5.3 box 1 -11 7. 5.3,box 10 : delete the statement of " see annex 1" 8. Form AF 01/007 : to include deviation… and Queries, Notifications and Complaints 9. References : • Delete link WHO • Delete FERCAP SOP
MW,LSH,IS	01.5	02 January 2022	1. Move "Glossary"into one page 2. Section 7 become Section 6, Section 8 become section 7 3. 2. Scope : add Protocol Deviation 4. Item 5.2.1.1, add box 1 : Ensure PIs have submitted Final report of the previous studies before submitting new protocol 5. Item 5.2.1.7 : Add detail instruction for Protocol Deviation 6. Item 5.2.4, add box 8 : Assign a running number to the received protocols, applying the system of 10 digits. The first four digits indicate the last two digits of the year, followed by number of the

			month. The next three digits are the running number of the year followed by institution code, and type of protocols (Clinical and Non Clinical Trial). 01 for protocol from MRIN, 02 from Faculty of Medicine (FoM)-Universitas Pelita Harapan (UPH), 03 from Siloam Hospitals, 04 from Faculty of Nursing, Universitas Pelita Harapan, 05. Department of Biology, Universitas Pelita Harapan, 06. Others. A, for clinical protocol. B,for Non-clinical protocols For example 2201001-01A means the first protocol submitted in January 2022 from MRIN for Clinical Trial 7. Item 5.2.4 : delete "count for correct numbers of copies" 8. Item 5.2.4 box 2 delete the word of "match the copy submitted by comparing a hard copy of the electronic document with the submitted one. " 9. Item 5.2.4 box 7 : changed department biology to be Faculty of Science and Technology 10. References : add Declaration of Helsinki 2013 & CIOMS 2016