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1. Purpose

To provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the EC of MRIN

2. Scope

This SOP applies to all active study files and their related documents that are maintained in the EC office.

3. Responsibility

It is the responsibility of EC/ Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. Flow chart

No.	Activity	Responsibility
1	Organize the contents of the active study files	MRIN EC Secretariat
	↓	
2	Maintain the active study files	MRIN EC Secretariat

5. Detailed instruction

5.1 Organize the contents of the active study files

- ☐ Get the master copy of the study files.
- ☐ Gather, classify and combine all related documents together.
- ☐ Check if a study file contains, at a minimum, the following documents:
  - Original applications and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
  - Adverse experience reports or IND safety reports received

- Continuing review reports

☐ Use a folder with the following on the cover:
- ☐ The name of the sponsor
- ☐ The protocol number
- ☐ The number assigned by the EC Secretariat

Put the following into each folder with the following information:
- Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone) and title
- Application form of the EC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator
  - Correspondence
  - Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
  - Revisions/Amendments
  - Adverse Events
  - Continuing Review, if applicable
  - Final report

5.2 Maintain the active study files

☐ Assign the approved study files with unique identifiers (on a sheet of paper/folder; orange marker for Approved Protocol, Black marker for Disapproved Protocol, Brown Marker for dropout protocols

☐ The Documents should be binding in Business File A4 :

1. Yellow for Faculty of Nursing UPH,
2. Green for Faculty of Medicine UPH
3. White for MRIN
4. Red for Biology
5. Blue for Others

☐ Combine related documents of the approved study files appropriately.
☐ Attach an identity Label to the active study file : Protocol Number, type of submission (Initial, Resubmission, Amendment,etc)
☐ Keep all active and potential active study file in a secure file cabinet.
☐ Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the MRIN EC.
☐ Send all closed study files to archive.
☐ Store the closed study files for at least 5 years after the study closure.

Note: For studies with multiple study sites, a member Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

6. Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Master file	A file for storage of the originally signed and dated documents
Dropout Protocol	Protocols under review and have not been approved by EC and that has not been resubmitted more than 3 months

7. Annex

Annex 1	AF/01-024/2020/01.3	Check List for Protocol File
Annex 2	AF/02-024/2020/01.3	Form Monitoring Protocol for MRIN EC Secretariat
Annex 3	AF/03-024/2020/01.3	Document History

8. 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.
- SIDCER Self-Assessment Tool, http://www.fercap-sidcer.org/selftool.php, accessed January 2013.

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Check List for Protocol File

1. Protocol Status - New - Amendment - Continuation		
2. Date of Submission		
3. Date of Receipt		
4. Recipient		
5. Participating Institution		
6. Protocol Number		
7. Protocol Title		
8. Principal Investigator		
9. Contact Person		
10. Timeline		
11. Document completeness	Yes	No
- Protocol		
- Cover Letter from referring institution		
- Original Proposal		
- Research Proposal Summary		
- Information for Subject		
- Informed Consent Form		
- CV of Principal Investigator		

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- Memorandum of Understanding between Sponsor and Research Institution (for Research Collaboration)		
- Ethical Approval from other Institution (when available)		
- Research Description		
- Material and Methods		
- Case Report Form/ Incidence Card		
- Forms: Questionnaire, Laboratory/ Radiology Examination Request, Laboratory/ Radiology Examination Results		
- Adverse Event Report Form		
- Investigator's Brochure (when necessary)		
- Investigational Drugs Approval from BPOM (New Drugs/ Food Trial)		
- Budgeting Detail and Funding Resourches		
- Others (e.g. Workflow)		

Secretariat MRIN Ethics Committee

Officer's signature

Annex 2
Form AF/02-024/2020/01.3

Form Monitoring Protocol for MRIN EC Secretariat

Document	Date	Remarks
Cover Letter from referring Institution		
Protocol Submission Form and copies (SOP 010. Annex 3, 4 or 5)		
Application Form for Initial Review (SOP 010 Annex 1)		
Study Assessment Form (SOP 008. Annex 1 / Annex 2)		
Assessment Report (SOP 008. Annex 3)		
MRIN EC Decision Form (SOP 008. Annex 4)		
Resubmission Form (SOP 010. Annex 3, 4 or 5)		
Review of Resubmitted Protocol Form (SOP 012. Annex 1)		
MRIN EC Decision Form (SOP 008. Annex 4)		
2nd Resubmission Form (SOP 010. Annex 3, 4 or 5)		
Review of 2nd Resubmitted Protocol Form (SOP 012. Annex 1)		
MRIN EC Decision Form (SOP 008. Annex 4)		
3rd Resubmission Form (SOP 010. Annex 3, 4 or 5)		
Review of 3rd Resubmitted Protocol Form (SOP 012. Annex 1)		
MRIN EC Decision Form (SOP 008. Annex 4)		
Ethical Approval		

Annex 3
Form AF/03-024/2020/01.3

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, Monalisa, Yan Nuryanto	01.2	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header
LSH,IS,MW, GE	01.3	02 January 2020	1. 5.1 : Delete the word of " Fax" 2. Add 5.2, Box 2 : The Documents should be binding in Business File A4 • Yellow for Faculty of Nursing, UPH • Green for Faculty of Medicine, UPH • White for MRIN • Red for Biology • Blue for Others 3. 5.2, box 1 : replace the approved study files with unique identifiers (on a sheet of paper from red marker becomes orange marker for approved protocol, black marker for disapproved protocol, and brown marker for dropout documents) 4. 5.2, Box 4 : replace the word of " package" with " active study file" 5. 5.2, Box 4 : add " Protocol Number, type of submission (Initial, Resubmission, Amendment,etc)" 6. 5.2, box 5 : replace the word of "

			package" with " active study file" an delete "potential active" 7. 6. Glossary Dropout Protocol 8. Annex 2 : to add another information, e.g …… ethical approval " 9. References : • Delete link WHO • Delete FERCAP SOP • Add ICH 2016