
	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 1 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Table of Contents

<u>No.</u>	<u>Content</u>	<u>Page No.</u>
	Table of Contents	1
1.	Purpose	2
2.	Scope	2
3.	Responsibility.....	2
4.	Flow chart.....	2
5.	Detailed instruction	2
5.1	After receiving the final report.....	2
5.2	When archiving administrative documents	3
5.3	Retrieving Documents.....	3
5.4	Disposal Documents.....	3
6.	Glossary.....	4
7.	Annex	5
8.	Reference.....	5
	Annex 1 Document Request Form	6
	Annex 2 Log of Requested MRIN EC Documents	7
	Annex 3 Disposal of Document Request Form	8
	Annex 4 Disposal of Document Form	9
	Annex 5 Document History	10

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 2 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

1. Purpose

To provide instructions for storing retrieval and disposal closed study files and other related documents in a secure manner while maintaining access for review by auditors and inspectors.

2. Scope

This SOP applies to archiving the closed study files and administrative documents that are retained for at least five years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors. Any documents that no longer required should be disposed in the manner described below. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of MRIN EC Secretariat for maintaining closed study files and other related documents.


4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	After receiving the final report ↓	MRIN EC Members, Secretariat
2	When archiving administrative documents ↓	MRIN EC Secretariat
3	Retrieving Documents ↓	MRIN EC Secretariat
4.	Disposal of Documents	MRIN EC Secretariat

5. Detailed instruction

5.1 After receiving the final report

- MRIN EC Secretariat and Members review the Final Report of the study.
- A member of the Secretariat should
 - remove the contents of the entire file from the active study filing area.

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 3 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

- verify that all documents are present in an organized manner.
 - obtain an archive number from the MRIN Archives Department.
 - enter the number into the file and the data base.
 - place the file in a storage container
 - send to the archives.
- Hold the files of multi-center studies, until all the study sites are closed.
 - Place in a storage container together.
 - Send to the archive.

5.2 When archiving administrative documents

A staff of the MRIN EC Secretariat should

- perform inventories of miscellaneous administrative documents
- place the documents in the appropriate storage container, and
- send it to the appropriate storage facility so that it may be easily retrieved.
- If the Investigator does not submit a final report, the protocol will be stored in inactive files after 90 days of MRIN EC reminders


Note: The EC Secretariat maintains past board membership information as well as the active administrative documents.

5.3 Retrieving Documents

- Keep in mind the SOP/026/2017/01.2 (Maintaining Confidentiality of Ethical Review Committee Documents)
- Retrieval of documents can only be done with a request form (AF/01-025/2020/01.3, see ANNEX 1) signed and dated by the MRIN EC Chairperson or the Secretariat.
- The requestor must also sign and date the log of request (AF/02-025/2020/01.3, see ANNEX 2)
- The Secretariat retrieves archived documents in compliance with the procedures of the MRIN Archives department and refers to the inventory kept by MRIN
- Return the file back to its place.
- Record, sign and date when the document has been returned and kept.

5.4 Disposal of Documents

- Documents should be destroyed after request form for destruction of documents was filled out and submitted (AF/03-025/2020/01.3). The principle for destruction of documents shall be in accordance with

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 4 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

SOP/026/2017.01.2 (Maintainance of MRIN EC documents confidentiality)

- The request form for destruction of documents needs to be signed by the Chair person MRIN EC as written evidence of consent for document disposal.
- Documents that may be destroyed are copies of original documents from completed protocol (i.e. copies of submitted initial review or documents related to continuing review)
- Documents to be destroyed should be recorded in the Disposal of Document Form (AF/04-025/2020/01.3) which contains record of title and versions of the documents, number of copies, place and date of disposal, tool for disposal, and name/ signature of person who disposes the documents.
- Copies of protocol documents shall be destroyed using paper shredder at the MRIN EC office, and this shall be conducted by EC Secretariat
- After the documents have been destroyed, Disposal of Document Request Form and Disposal of Document Form should be included in the original documents files (as substitute for the destroyed documents)


6. Glossary

Administrative Documents Documents include official minutes of Board meetings (as described in SOP/021/2020/01.5 and the Standard Operating Procedures, both historical files and Master Files as described in SOP/001/2020/01.3.

Closed Study Files Approved and supporting documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the Board for which a final report has been reviewed and accepted.

Disposal of Documents The process by which any documents that is no longer required

Dropout of Protocols Drop out protocols : Protocols under review and have not been approved by EC and that has not been resubmitted more than 3 months

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 5 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

7. Annex

Annex 1	AF/01-025/2020/01.3	Document Request Form
Annex 2	AF/02-025/2020/01.3	Log of Requested MRIN EC Documents
Annex 3	AF/03-025/2020/01.3	Disposal of Document Request Form
Annex 4	AF/04-025/2020/01.3	Disposal of Document Form
Annex 5	AF/05-025/2020/01.3	Document History

8. References

- 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.
- Associated SOPs: SOP/026/2017/01.2.

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 6 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Annex 1

Form AF/01-025/2020/01.3

Document Request Form


Name of Document requested:		Code:
Requested by:		Date:
<input type="checkbox"/> Chairperson <input type="checkbox"/> Secretariat <input type="checkbox"/> MRIN EC Member		
<input type="checkbox"/> Secretariat staff <input type="checkbox"/> Authority <input type="checkbox"/> Others.....		
Purpose of the request:		
Retrieved by:		Date:
Returned by:		Date:
Archived by:		Date:
Approved by:		Date:

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 7 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Annex 2
Form AF/02-025/2020/01.3

Log of Requested MRIN EC Documents

#	Document	Requester	Date Requested	Retrieved by	Archived by	Returned Date

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 8 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Annex 3
Form AF/03-025/2020/01.3

Disposal of Document Request Form


Name of Document requested:		Code:
Secretariat		Date:
Purpose of the request:		
Methode of Disposal :		
Approved by :		Date :
Retrieved by:		Date:
Disposed by:		Date:
Archived by:		Date:
Approved by		Date :

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 9 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Annex 4
Form AF/04-025/2020/01.3

Disposal of Document Form

Name of Disposed Documents :	Code:
Person who disposed the documents :	Date:
Method of Disposal :	
Archived by :	Date :
Approved by :	Date :

	Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)	SOP/025/2020/01.3 Effective date: 02 January 2020 Page 10 of 10
	<u>Title:</u> 025. Archives and Retrieval of Documents	

Annex 5
 Form AF/05-025/2020/01.3

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	Final version
Ivet, Lia, Mona	01.1	11 October 2014	<ol style="list-style-type: none"> 1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Irawan Yusuf, Debbie S. Retnoningrum	01.2	1 April 2017	<ol style="list-style-type: none"> 1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header
MW,LSH,IS, GE	01.3	2 January 2020	<ol style="list-style-type: none"> 1. 5.2, box 4 : to Add statement “if the PI did not submit a final report, The protocol will be stored in inactive file after 90 days of MRIN EC Reminder” 2. 6. Glossary : add “ Drop Out of Documents : Protocols under review and have not been approved by EC and that has not been resubmitted more than 3 months” 3. References : <ul style="list-style-type: none"> • Delete link WHO • Delete FERCAP SOP • Add ICH 2016