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1. Purpose

This procedure describes how an MRIN EC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the MRIN EC, Data Safety Monitoring Board (DSMB), Scientific Director, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by MRIN EC that is being recommended for termination before its scheduled completion.

3. Responsibility

It is the responsibility of the MRIN EC Chairperson to terminate any study that the MRIN EC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process. The review of the Study Termination Report should be done by Primary Reviewers

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Receive recommendation for study termination ↓	Members or MRIN EC Secretariat
2	Review and Discuss the Termination Package ↓	MRIN EC Members and Chairperson
3	Notify the Principal Investigator ↓	MRIN EC Secretary
4	Store the Protocol Documents ↓	MRIN EC Secretariat
5	Inactivate the Protocol Document	MRIN EC Secretariat

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5. Detailed instructions

5.1 *Receive recommendation for study termination.*

- Receive recommendation and comments from DSMB, MRIN EC members, Sponsor, Principal Investigator or other authorized bodies for study protocol termination.
- Inform the principal investigator or the study office to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principal investigator or the study office.
- Verify the contents of the package for inclusion of:
 - Request for Study Termination Application (AF/01-018/2020/01.5)
 - The request for Study Termination Application should contain a brief written summary of the protocol, its results, management of enrolled subject and accrual data.
 - Original Continuing Review Application Form (AF/01-014/2020/01.6).
 - Termination is indicated under “Action Request”.
 - Completeness of the information, including accrual data since the time of the last continuing review.
 - Presence of the required signatures (Principal Investigator).
- Initial and date the package upon receipt.

5.2 *Review and discuss the Termination Package.*

- Notify the Chairperson/ Vice chairperson/Secretary regarding the recommendation for study protocol termination.
- Send a copy of the termination package to the Chairperson/Vice chair person Secretary within 1(one) working day upon receipt.
- The Chairperson/ Vice chairperson/Secretary reviews the results, reasons and accrual data.
- The Chairperson/Vice chairperson/Secretary can call for an emergency meeting to discuss about the recommendation if needed.
- The MRIN EC members will decide to suspend or terminate the study
- The Chairperson signs and dates the Continuing Review Application Form in acknowledgment and approval of the termination.

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- The Chairperson returns the form back to the Secretariat within 5 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Continuing Review Application Form indicating that the termination process is complete.

5.3 *Notify the Principal Investigator.*

- Make a copy of the completed Continuing Review Application Form
- Send the copy to the principal investigator for their records within 7 working days.

5.4 *Store the protocol documents.*

- Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
- Send the file to archive.
- Store the protocol documents indefinitely.

5.5 *Inactivate the protocol documents.*

- Place the study protocol into the *inactive* protocol folder in the computer records under the following directory:
F:\studyfiles\inactive protocols

6. Glossary

Suspension	Stop until further clarification
Termination	Permanently stop of the study

7. Annex

Annex 1	AF/01-018/2020/01.5 Study Termination Application
Annex 2	AF/02-018/2020/01.5. 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

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- 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. DELETE
- International Conference on Harmonisation (ICH) Harmonised Tripartite : Guideline for Good Clinical Practice E6(R1), Current Step 4 version dated 10 June 1996, November 2005.
- Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44. DELETE
- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.DELETE
- SIDCER Self-Assessment Tool, <http://www.fercap-sidcer.org/selftool.php>, accessed January 2013.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016. TAMBAHAN
- Associated SOP: SOP/014/2020/01.6.
- Standard Operating Procedures UP Manila,2019

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Annex 1
 Form AF/01-018/2020/01.5
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Study Termination Application

PROTOCOL NUMBER:			
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
MRIN EC APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
Reason for Early Termination			
SUMMARY OF RESULTS			
ACCRUAL DATA: How many have completed the study? How many subject of			

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research are still active? Plans for those who are still active in the study		
P.I.SIGNATURE:		DATE:
Assessment by the Primary Reviewer : (any issue related to participant safety?)		
DECISION : 1. APPROVED 2. SUSPEND 3. NOT APPROVED		
SIGNATURES: _____ Date:..... Protocol Reviewer		
APPROVAL: _____ Date: Chairperson, MRIN EC		
COMPLETION: _____ Date:..... Secretary, MRIN EC		

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Annex 2
Form AF/02-018/2020/01.5

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	Final version
Ivet, Lia, Mona	01.1	11 October 2014	<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 3. Section 5.2. : Post approval documents should be reviewed by the primary reviewers 4. Annex 1 : addition of section for reviewer's signature
Ivet, Lia, Mona	01.2	15 November 2014	<ol style="list-style-type: none"> 1. Section 5.2. "Post Approval Documents" replace with " Study Termination Report" 2. "The review of Study Termination Report should be done by the Primary Reviewer" in Sec 3
Liliana Kurniawan, Dondin Sajuthi	01.3	1 April 2017	<ol style="list-style-type: none"> 1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.2. box 2: Replace "5 working days" to "1 (one) working day"
LSH/MW/IS	01.4	2 January 2019	<ol style="list-style-type: none"> 1. Item 5.1 Box 4 and Annex 1 : to add enroll management subject 2. Item 5.1 Box 4 and Annex 1: Replace Termination Memorandum with Termination Application 3. Item 5.2 : to ad Vice chairperson
MW,GE,LSH, IS	01.5	2 January 2020	<ol style="list-style-type: none"> 1.5.1. Box 4 : Delete management of enrolled 2. Annex : add ; reason, accrual data and Delete Assigned no. 3. References : <ul style="list-style-type: none"> • Delete link WHO • Delete FERCAP SOP

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			<ul style="list-style-type: none"> • Add ICH Nov 2016
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