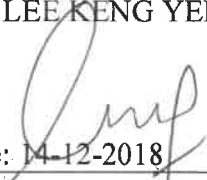
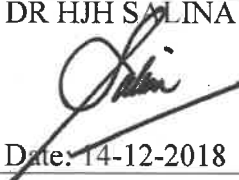


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Standard Operating Procedure Maintenance, Archival and Disposal of Study and Non-Study Files

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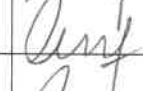

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0	All	01/03/2011	Version 1.0, first issue	
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1. PURPOSE

This standard operating procedure is to provide instructions for preparation and maintenance of active study files and other related documents, storing of closed files, retrieval of documents, and record keeping of MREC activities in accordance with applicable regulatory and institutional requirement.

2. SCOPE

This SOP applies to all study files and associated documents, administrative correspondences, and closed files that are maintained in the office of Medical Research & Ethics Committee (MREC).

3. ABBREVIATIONS

ArvSF	Archived Study File
ASF	Active Study File
CSF	Closed Study File
MREC	Medical Research and Ethics Committee
NIH	National Institute of Health, Malaysia
NSF	Non-Study Files

4. GLOSSARY

Term	Definition
Active Study File	File containing documents of a study that is being processed for approval, or is ongoing.
Archived Study File	Closed study files which have exceeded 5 years storage period, and are to be destroyed.
Closed Study File	File containing documents of a study that has been completed or terminated or discontinued.
Completed study	A study that is stopped because all study procedures as stated in the protocol have been done and finished.
Discontinued study	A study that is stopped by the investigator and informed to regulatory authority, IRB and/or sponsor
Terminated study	A study that is stopped by instructions of a regulatory authority, IRB or sponsor

5. REQUIRED AND RELATED DOCUMENT

#	Document Title
1.	SOP 1-2: Confidentiality and Conflict of Interest Agreement
2.	SOP 2-3: Initial Full board Review
3.	SOP 4-1: Preparation of Agenda, Meeting Procedures and Minutes
4.	WS 5-1-6: Register for Archival and Disposal of Study Files
5.	WS 5-1-7: Record of Access to Study Files
6.	WS 5-1-8: Register for Non-study Files
7.	WS 5-1-9: Register for closed Non-study Files
8.	WS 5-1-10: Register for storage and Disposal of Non-study Files
9.	TP 5-1-1: Application for Administrative Access

6. PROCEDURE

6.1. Maintenance, Archival and Disposal of Study Files

Step #	Process	Responsibility
1.	Receives NMRR alert of New Research submission and instructs Secretariat to take action.	Secretary
2.	Check completeness. If complete, assign Serial Project Number via NMRR system. All study documents and correspondence in chronological order will be retained in NMRR system.	Secretariat
3.	NMRR system is updated when: a) Study is completed, or b) Study is terminated, or c) Study is discontinued	Secretariat
4.	All study documents will be stored and archived in NMRR system.	Secretariat
5.	Disposal of digital archived files in NMRR system minimum of 3 years after study completion. Digital files may be retained for a longer period of time if storage is sufficient.	Secretariat

6.2. Maintenance, Archival and Disposal of Non-study Documents

Step #	Process	Responsibility
1.	Receives and date stamps document	Secretariat
2.	Identifies appropriate NSF. If file not available, opens new file and obtains file reference number from file clerk	Secretariat
3.	Records date of creating the file on the front cover of the file.	Secretariat
4.	Create an Index Page according to Section 8.1.5 and using a " KERTAS MINIT " (Appendix 1)	Secretariat
5.	Keeps a copy of all correspondence in chronological order. Records all entries in the index page according to Reference 8.3 .	Secretariat
6.	Records any movement of NSF on the front cover of the file and in a " KAD PERGERAKAN FAIL " Appendix 2 .	
7.	Closes NSF when it meets the criteria in Section 7.5.6.1 and records details in WS 5-1-9 . Go to step 3 to open new volume if necessary.	Secretariat
8.	Transfers the closed NSF to storage area and records details in WS 5-1-10	Secretariat
9.	Identifies closed NSF stored more than 7 years and request for disposal using the Form Arkib 5/08 (Appendix 3)	Secretariat
10.	Upon approval, disposes NSF and updates WS 5-1-10	Secretariat

7. DETAILED INSTRUCTIONS

7.1. Maintenance of Active Study Files (ASF)

- 7.1.1. The Secretariat instructs Secretariat staff to establish a new ASF on receiving a **NMRR alert of New Research submission**.
- 7.1.2. Secretariat keeps a copy of all the relevant study documents and correspondence in chronological order, in the NMRR system with audit trail.
- 7.1.3. Secretariat maintains and stores active study files digitally in a traceable manner, according to the sequence of the **Serial project number**, within a secured server system with controlled access.
 - 7.1.3.1. Secretary keeps a list of persons who are able to access to the study files.
 - 7.1.3.2. Persons who are authorized to access study files may log in to NMRR system using password. Access will be traceable via NMRR tracking system.
- 7.1.4. NMRR system records closing study file when:
 - 7.1.4.1. Study is completed, or
 - 7.1.4.2. Study is terminated, or
 - 7.1.4.3. Study is discontinued
 - 7.1.4.4. Study ethical approval is expired

7.2. Storage of Closed Study Files (CSF)

- 7.2.1. All study files must be stored for at **least 3 years** following study closure.
- 7.2.2. All study files may be retained for a longer period of time in NMRR system if storage is sufficient.

7.3. Storage and Disposal of Archived Study Files (ArvSF)

- 7.3.1. Secretariat transfers files to digital storage area for ArvSF and records details in **WS 5-1-6**.
- 7.3.2. Secretariat disposes ArvSF and records disposal in **WS 5-1-6**.

7.4. Access to Records / Retrieval of Document / Record Keeping

- 7.4.1. Access to all Study Files is limited to the MREC Chairperson/Deputy Chairperson/Secretary, MREC Secretariat, MREC members, regulatory agencies and accrediting bodies. Other individuals can request for access following **Section 7.4.4** below. All individuals accessing Study Files must abide by **SOP 1-2**.
- 7.4.2. Investigators or their authorized study personnel may access their own study files by submitting an administrative request (**TP 5-1-1**).
- 7.4.3. Administrative requests for access must be in writing and contain the following information:
 - 7.4.3.1. The name of the person requesting the information;
 - 7.4.3.2. The Documents requested;
 - 7.4.3.3. The reason for the request;
 - 7.4.3.4. Whether a copy of the document(s) is required and in what format.

7.4.4. Upon receipt of an administrative request, the Secretary examines the request and decided whether access is permitted and copying the document(s) is allowed.

7.4.4.1. If obtained photocopy is requested and is allowed by the Secretary, the secretariat makes a copy of the requested documents for pick up by the applicant. As per government regulations, the applicant will make payment for the photocopies to the **NIH Finance Unit**. The photocopy (ies) will be handed over to the applicant when an official payment receipt is produced.

7.4.5. Individuals who are not authorized by the principal investigator and/or sponsor (for ISRs) shall not be permitted access to Study Files. It is the responsibility of such individuals to obtain the relevant authorization before submitting an administrative request as per **Section 7.4.4** above.

7.5. Create, maintenance, storage and disposal of Non-study Documents

7.5.1. The Secretariat creates, maintains and stores non-study Documents in files or binders, as appropriate for the following documents, but are not limited to:

- 7.5.1.1. Standard operating procedures;
- 7.5.1.2. MREC membership files;
- 7.5.1.3. MREC membership rosters;
- 7.5.1.4. Communication Records (including all official letters)
- 7.5.1.5. Meeting agenda and minutes
- 7.5.1.6. Alleged non-compliance case records;
- 7.5.1.7. Any mandated reports

7.5.2. MREC secretariat creates a new file when:

- 7.5.2.1. The file required is not created yet
- 7.5.2.2. Original file is closed and continued to a new volume
- 7.5.2.3. Original file cannot be traced
- 7.5.2.4. Original file is found to be worn and needs to be replaced; a new file is reproduced or a new volume is created
- 7.5.2.5. Change in office administration
- 7.5.2.6. Change in file classification system

7.5.3. Creating new non-study file

7.5.3.1. A new file is created upon finding no suitable and available file for a new non-study document.

7.5.3.2. Secretariat obtains a suitable new file number from the NIH file clerk.

7.5.3.3. File clerk labels each NSF at the center of the front cover with the < *File Title* > and at the top right corner with the < *File number* > in black or blue ink. Secretariat records the date of filing of the first document at the section “*tarikh kandungan pertama*” at the front cover of the NSF.

7.5.3.4. File clerk registers the new NSF in **WS 5-1-8**.

7.5.4. Filing and maintenance of non-study files

- 7.5.4.1. Secretariat date stamps each new non-study document received. As far as possible, the original copy of the document is filed and a photocopy made for distribution purpose or for action to be taken.
- 7.5.4.2. File clerk records the details of the document received in the **Index page** (see **section 8.1.5**).
- 7.5.4.3. As far as possible, documents are filed in sequential order based on receipt date.
- 7.5.5. File clerk records any movement of NSF on the front cover of the file by stating the abbreviated name of the recipient at the section '*dihantar kepada*' and the date document was sent at section '*tarikh dihantar*'.

7.5.6. Closure of Non-study File

- 7.5.6.1. In accordance with **Reference 8.3**, a NSF is closed when:
 - 7.5.6.1.1. Thickness of file reaches 4cm; or
 - 7.5.6.1.2. Contains 100 documents;
 - 7.5.6.1.3. File not referenced for 5 years and not required for daily administration;
 - 7.5.6.1.4. **File closed and no further action** is required on the documents
 - 7.5.6.1.5. Any Administrative changes in the office
 - 7.5.6.1.6. MREC ceased operation
 - 7.5.6.1.7. Changes in files classification
- 7.5.6.2. File clerk closes the file via the following manner:
 - 7.5.6.2.1. For NSF that are closed due to criteria in sections **7.5.6.1.1** and **7.5.6.1.2**, File clerk strikethroughs the cover of the files in Red with the following statement in black or blue:
TUTUP PADA <date>, SILA LIHAT JILID <Volume number> (SAMBUNGANNYA).
 - 7.5.6.2.2. For NSF that are closed due to sections **7.5.6.1.3** to **7.5.6.1.6**, file clerk strikes through the cover of the files in Red with the following statement 'TUTUP PADA <date>' in black or blue.
 - 7.5.6.2.3. For NSF closed due to section **7.5.6.1.7**, file clerk strikes through the cover of the file in Red, with the statement 'TUTUP PADA <date>, SILA LIHAT SKEMA KLASIFIKASI FAIL BAHARU' in black or blue.
- 7.5.6.3. File clerk transfers closed NSF to designated store and records details in **WS 5-1-9**. Closed NSF are stored at least 5 years.
- 7.5.6.4. File clerk compiles a list of closed NSF of more than 5 years to be destructed, and request for disposal (see **APPENDIX 3**) from the Director of NIH, as per the National Archive Act 2003
- 7.5.6.5. Upon approval, file clerk disposes files and records disposal in **WS 5-1-10**.

8. REFERENCES

- 8.1. Malaysian Guideline for Good Clinical Practice, 4th Edition, Ministry of Health.
- 8.2. International Conference on Harmonization, Guideline on Good Clinical Practice (ICH GCP) 1996
- 8.3. Laws of Malaysia, Act 629, National Archives Act 2003.
- 8.4. Arkib Negara Malaysia, Panduan Pengendalian Fail Rasmi, 2012.
- 8.5. Arkib Negara Malaysia, Panduan Pelupusan Rekod Awam, 2010.

9. APPENDIX

- 9.1. Appendix 1: Kertas minit
- 9.2. Appendix 2: Kad pergerakan Fail
- 9.3. Appendix 3: Borang Permohonan Bagi Pelupusan Fail

APPENDIX 1

KERTAS MINIT

Kertas Minit No.	Helaian No.
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____
	Surat Bil _____ bertarikh _____ Dihantar kepada/ Daripada _____ pada _____ / dimasukkan pada _____

APPENDIX 3

[Subperaturan 7(3)]

Borang 5

Arkib 5/08


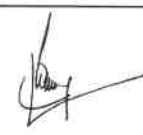
BORANG PERMOHONAN BAGI PELUPUSAN FAIL
(YANG TIDAK DINYATAKAN DALAM JADUAL PELUPUSAN REKOD)

BUTIR-BUTIR JABATAN				Untuk Kegunaan Arkib Negara			
(1) Kementerian/Jabatan/Agensi:		(2) Bahagian/Cawangan/Unit:		Tarikh Terima: Jumlah Fail: No. Penerimaan:			
(3) Pewujud Rekod [Jika tidak sama dengan (1)]:							
MAKLUMAT MENGENAI REKOD							
(4) Kategori Rekod: <input type="checkbox"/> Fungsian <input type="checkbox"/> Am			(5) Peringkat Keselamatan:				
(6) Tarikh Diliputi:			(7) Ukuran Rekod: (meter panjang.)				
Bil. (8)	No. Rujukan Fail (9)	Tajuk Fail (10)	Tarikh (11)		Bil. Lampiran (12)	Cadangan Pelupusan (13)	Catatan (14)
			Daripada	Kepada			
(15) Mengikut Seksyen 25 dan 26, Akta Arkib Negara 2003 [Akta 629], saya mengemukakan permohonan ini bagi pelupusan rekod di atas: Nama Pegawai: _____ Tandatangan/Meterai/Cap Jabatan: _____ Jawatan: _____ Tarikh: _____							

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Record for Archival and Disposal of Study Files**

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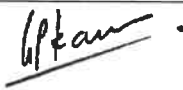

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Register for Closed Non-Study Files**

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