CHAPTER 9.2

ARCHIVES AND RETRIEVAL OF DOCUMENTS

SOP NUMBER: SOP/026/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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Approved by: Chairperson, IRB — Date: September 30, 2021
Name: ***Dr. Karma Tenzin***

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1. PURPOSE

The purpose of this SOP shall be to provide instructions for storing *inactive* study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

2. SCOPE

This SOP shall apply to archiving the 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 future reference. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. RESPONSIBILITY

The IRB Secretariat shall be responsible for maintaining inactive study files and administrative documents.

4. FLOW CHART

No.	Activity	Responsibility
1	After receiving the final report ↓	IRB members, secretariat
2	When archiving administrative documents ↓	IRB secretariat
3	Retrieving Documents	IRB secretariat

5. DETAILED INSTRUCTION

5.1. After receiving the final report

5.1.1. IRB Secretariat and Members shall review the Final Report of the study.

5.1.2. A member of the Secretariat shall:

- 5.1.2.1. Remove the contents of the entire file from the active study filing area.
- 5.1.2.2. Verify that all documents are present in an organized manner.
- 5.1.2.3. Assign an archive number
- 5.1.2.4. Enter the number into the file and the data base.
- 5.1.2.5. place the file in a storage container
- 5.1.2.6. Send to the archives.

5.1.3. Hold the files of multi-centre studies, until all the study sites are closed.

5.1.4. Place in a storage container together.

5.1.5. Send to the archive.

5.2. When archiving administrative documents

5.2.1. A staff of the IRB Secretariat shall:

- 5.2.1.1. perform inventories of miscellaneous administrative documents
- 5.2.1.2. place the documents in the appropriate storage container, and
- 5.2.1.3. Send it to the appropriate storage facility so that it may be easily retrieved.

Note: The IRB Secretariat shall maintain past committee membership information as well as the active administrative documents.

5.3. Retrieving Documents

5.3.1. Keep in mind the SOP/026/01 (Maintaining Confidentiality of IRB documents)

5.3.2. Retrieval of documents can only be done with a request form (AF/01-026/01, see ANNEX 1) signed and dated by the IRB Chairperson or the Secretariat.
5.3.3. The requestor shall also sign and date the log of request, ANNEX - AF/02-026/01
5.3.4. The Secretariat shall retrieve archived documents in compliance with the procedures of the IRB.
5.3.5. Return the file back to its place.
5.3.6. Record, sign and date when the document has been returned and kept.

6. GLOSSARY

Administrative Documents	Documents include official minutes of committee meetings (as described in SOP/022/01) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/001/01.
Inactive 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 IRB for which a final report has been reviewed and accepted.

7. REFERENCES

7.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
7.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016
7.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants, 2011.
7.4. Associated SOPs: SOP/026/01.

8. ANNEX

ANNEX 1	AF/01-026/01	Document Request Form
ANNEX 2	AF/02-026/01	Logs of Requested IRB Documents

ANNEX 1
AF/01-026/01

Document Request Form

Name of Document requested:	Archive No:
Requested by:	Date:
☐ Chairperson ☐ Secretariat ☐ IRB Member	
☐ Secretariat staff ☐ Authority ☐ Others……..	
Purpose of the request:	
Approved by:	Date:
Retrieved by:	Date:
Returned by:	Date:
Archived by:	Date:

ANNEX 2
AF/02-026/01

Log of Requested IRB Documents

No	Document	Requester	Date Requested	Retrieved by	Archived by	Returned Date

Page No…….