CHAPTER 9.3

MAINTAINING CONFIDENTIALITY OF IRB'S DOCUMENTS

SOP NUMBER: SOP/027/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. SCOPE

This SOP shall apply to all kinds of handling, distribution and storage of submitted study protocols, IRB documents, and correspondence with experts, auditors and the general public.

3. RESPONSIBILITY

Confidentiality of study protocols, IRB documents, and correspondence with experts and auditors is mandatory. IRB members and staff shall be required to sign confidentiality agreements with the KGUMSB.

If non-members of the IRB need copies of documents, the IRB member/staff requesting a copy on behalf of the non-members shall be responsible to maintain confidentiality of documents.

4. FLOW CHART

No.	Activity	Responsibility
1	Access to IRB documents ↓	IRB members and Secretariat
2	Classify confidential documents ↓	IRB members and Secretariat
3	Copy confidential documents ↓	IRB Secretariat
4	File Log of Copies	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Access to IRB Documents

The IRB members and the staff of the Secretariat of the IRB shall **read, understand and agree to the following:**

5.1.1. Members of the IRB shall:

5.1.1.1. Sign a confidentiality agreement (AF/01-004/01) with the IRB at the KGUMSB before the start of any activity of the IRB.

5.1.1.2. Have access to all IRB documents.

5.1.1.3. Be free to request and to use original documents or copies of original documents.

5.1.2. Secretariat of the IRB

5.1.2.1. The member secretary of the IRB is a staff member of the MECRIT, KGUMSB

5.1.2.2. Sign a confidentiality agreement with the IRB, KGUMSB

5.1.2.3. Have access to any document issued by or to the IRB, according to SOP/027/01 (Maintaining Confidentiality of IRB's Documents).

5.2. Classify confidential documents.

5.2.1. Types of documents

The types of documents reviewed by IRB members include:

5.2.1.1. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)

5.2.1.2. IRB documents (meeting minutes, advice and decisions)

5.2.1.3. Correspondence (experts, auditors, study participants, etc.)

Note: Copies of all versions of documents, including draft and sequential definitive versions are to be kept private and confidential with the exception of those made according to the following sections.

5.3. Copy of confidential documents

Copies of documents, including draft and sequential versions, shall be considered to be confidential and shall not be permitted to be brought out *except when a document is needed for day-to-day operations.*

5.3.1. Copy Authorization

5.3.1.1. Only members of the IRB shall be allowed to ask for copies.

5.3.1.2. Only staff members of the Secretariat of the IRB shall be allowed to make such copies.

5.3.1.3. The Member Secretary of the IRB may ask for help, but shall be responsible for maintaining confidentiality of all documents.

5.3.2. Log of Copies

5.3.2.1. A Log of Copies (see ANNEX 1 Form AF/01-027/01) shall be kept by the Secretariat.

5.3.2.2. The log should include: the name and signature of the individual receiving the copy; the initial of the IRB Member Secretary who made the copy; the number of copies made and the date that the copies were made.

5.3.3. Copies requested by non-members of the IRB

5.3.3.1. Copies of IRB's documents requested by non-members of the IRB (including the Member Secretary) shall be given upon prior permission from the Chairperson of the IRB and the person requesting for the document signs a confidentiality agreement form (AF/01-004/01).

5.3.3.2. Copies made for non-members of the IRB shall be recorded in both the Log of Requests for Copies of IRB's documents (AF/01-027/01) and the log of Copies of the Original Documents (AF/02-027/01).

5.4. File Log of Copies.

5.4.1. The Log of Copies of Original Documents shall be stored with the original documents.

5.4.2. The Log of Copies of Original Documents shall not be a confidential document and shall be reviewed upon request.

5.4.3. A Log of Copies of Original Documents shall be maintained.

6. GLOSSARY

Document	Documents mean the followings: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IRB documents (SOPs, meeting minutes, advice and decisions) - Correspondance (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Non-members of the IRB	Any relevant person/persons who presently is/are not a member/members of the IRB such as authorities, monitors, auditors, subjects, etc.

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/004/01

8. ANNEX

ANNEX 1 AF/01-027/01 Log of Requests for Copies of IRB documents
ANNEX 2 AF/02-027/01 Logs of Copies of Original Documents

ANNEX 1
Form AF/01-027/01

Log of Requests for Copies of IRB Documents

No	Documents requested	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

ANNEX 2
Form AF/02-027/01

Log of Copies of Original Documents

Title of the Document:……

No	Name of Recipient	# of Copies	Reasons of the Request	Signature of Recipient	Secretariat Initials	Date

Note: *This log should be attached to the original documents.*