養和醫療
HKSH Medical Group

倫理委員會(研究)記錄管理標準操作規程
Standard Operating Procedure for Records Management for Research Ethics Committee

Revision Summary of the Last Revision

Version	Revision Details	Relevant Section	Effective Date
01	Initial release	N/A	17 July 2018
03	Revised format	Whole document	8 October 2019
04	Added records retention sop for clinical trials / clinical research studies	Section 5.3.4	15 August 2024

Document Locations and Distribution if any

Controlled Soft Copy	Policy Portal in HKSH Medical Group

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15 August 2024

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Approved by Chairman	:	15/08/2024
First Issued	:	17/07/2018
Next Review	:	August 2026
Risk Rating		N/A

倫理委員會(研究)記錄管理標準操作規程
Standard Operating Procedure for Records Management for Research Ethics Committee

1 Objective

This Standard Operating Procedure (SOP) sets out the requirements for maintaining and preserving the records of the Research Ethics Committee (REC) of the HKSH Medical Group.

2 Scope and Definition

This SOP is applicable to the documentation of REC's SOPs, meetings, decisions, and research study applications.

3 Responsibility

The REC Secretary is responsible for the documentation of REC's SOPs, meetings, decisions and research study applications.

4 Training and Qualification

Not Applicable

5 Procedure Details (Maintenance of Records)

5.1 Electronic Database

5.1.1 An electronic database for all research study applications submitted to the REC for review shall be established and maintained by the REC Secretary.

5.1.2 The database should contain information about all research study applications (including approved, disapproved, ongoing, completed, and prematurely terminated studies), including but not limited to:

(a) REC reference numbers;
(b) Names and departments of principal investigators;
(c) Application identifiers (e.g. study titles);
(d) Dates of initial submission;
(e) Dates of approval / disapproval;
(f) Dates of study completion;
(g) Dates of last progress report submission;
(h) Current status of the study.

5.1.3 The REC Secretary is responsible for maintaining the database and supplying data therein to any governing body(ies) when necessary.

5.2 Records Retention

5.2.1 The REC Secretary shall retain all necessary documents and records relating to research studies, including but not limited to:

(a) documents and records relating to initial review of the studies (e.g. initial Research Study Application Forms, study documents submitted by the investigators, review meeting agendas and minutes, list of reviewers and their conflict of interest declarations, relevant correspondences between the REC and investigators, and REC written decision(s)/opinion(s));

(b) documents and records relating to continuous oversight of the studies (e.g. records for review of amendments/additional information, new information or deviations/compliance incidents, progress reports and relating publications); and

(c) documents and records of study audits.

5.2.2 All records related to research study applications will be retained for at least 7 years after the completion, discontinuation, termination or withdrawal of the studies.

5.3 Confidentiality and security

5.3.1 The REC secretary shall sign the statement of confidentiality before discharging duties.

5.3.2 All documents must be stored in cabinet with lock inside REC secretariat with restricted access. All documents can only be accessed by the REC Secretary.

5.3.3 Electronic Database can be only accessed by the REC secretary with password protected personal account.

5.3.4 Records of clinical trials / clinical research studies

5.3.4.1 The duty to maintain records of clinical trials / clinical research studies rests with the principal investigator of the respective trial / study.

5.3.4.2 All research documents should be maintained in a secure, systematic and readily retrievable manner.

5.3.4.3 Physical research documents should be stored securely in places with controlled access for authorized persons only. Digital research documents should be stored in password protected devices with controlled access for authorized persons only. Appropriate measures should be implemented to prevent unauthorized or accidental access, use, change or loss.

5.3.4.4 If personal data are contained in research documents, the personal data should be maintained in compliance with the provisions of the Personal Data (Privacy) Ordinance (Chapter 486 of the Laws of Hong Kong). Investigators may consult the Office of the Privacy Commissioner for Personal Data for guidelines and measures to ensure compliance with the Ordinance.

5.3.4.5 The following Data Protection Principles set out in Schedule 1 of the Ordinance are of particular relevance:

Principle 2 – accuracy and duration of retention of personal data;

Principle 4 – security of personal data.

5.3.4.6 Research documents containing personal data should not be retained for longer than necessary for fulfilling the research purpose. Documents which are no longer necessary should be properly disposed of or destroyed to prevent disclosure of the personal data contained therein.

5.3.4.7 While there is no standard duration for which research documents should be retained, the principal investigator should determine the retention duration having regard to the nature and purpose of the study, the necessity for follow-up actions, and the retention period indicated (if any) in the research information provided to study subjects.

5.3.4.8 The principal investigator should notify the REC of the location of the retained documents. Where the documents have been disposed of or destroyed, the principal investigator should inform the REC of the date and manner of such disposal or destruction within 14 days. The REC secretary will perform spot check of completed studies if deemed necessary.

6 Record

Not Applicable

7 Attachment

Not Applicable

8 Reference Documents

Not Applicable