RESEARCH
Policy and Procedure

TITLE:	Retention of Research Records	**NUMBER:**	RS-RA-011
Sponsor:	VP Quality, System Performance and Transformation	Page:	1 of 6
Approved by:	VP Research, Innovation and Knowledge Translation	Approval Date: Effective Date:	2017-09-15 2017-09-15
Applies To:	Nova Scotia Health Authority Researchers, Research Teams and Research Services		

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POLICY STATEMENTS

1. The Principal Investigator (PI) must ensure that Research Records are retained in compliance with applicable Nova Scotia Health Authority (NSHA) regulatory, and sponsor requirements.
2. Research records must be stored on premises owned or leased by NSHA.

   2.1. Storage areas must be secure and should be organized for easy retrieval.
3. To ensure confidentiality, only the PI, department/division head, Research Ethics Board, or Research Services are authorized to retrieve stored records.
4. At the end of the applicable retention period, Research Records must be destroyed in accordance with NSHA standards regarding confidential waste paper disposal and electronic media destruction (e.g., shredding, pulverization).

GUIDING PRINCIPLES AND VALUES

1. Research Services offers record storage and retrieval services for researchers in the Central Zone, NSHA. Storage and retrieval fees may be applied.
2. Research Records are retained to enable subsequent evaluation of the conduct of the Research Study and the quality of the data produced, and to meet regulatory requirements.

PROCEDURE

1. Retention of Research Study Records

1.1. The PI or designate:

1.1.1. Determines NSHA, regulatory, and sponsor requirements for retaining Research Study records (see Records Management Guide for Research Records which contains retention schedules and periods for Research Records).

1.1.2. Liaises with applicable NSHA departments and services (e.g., pharmacy, laboratory, diagnostic imaging) to arrange for retention of pertinent records in accordance with research requirements.

1.1.3. Determines how records will be stored and the means by which prompt access will be assured.

1.1.4. Upon Research Study closure, discards duplicates, draft documents and copies of original records retained by others, and stores one copy of each remaining document as necessary.

2. Records Stored by Research Services in Central Zone

2.1. The PI or designate follows the record storage and retrieval processes outlined in Research Services' Records Management Guide for Research Records and the instruction sheet "*So you want to store some research records? Here's how*."

2.2. Research Services manages (receives, stores, retrieves, destroys, and tracks) records in accordance with the Records Management Guide for Research Records and the instruction sheet "*So you want to store some research records. Here's how*."

3. Records Not Stored by Research Services

3.1. If the PI decides **not** to use Research Services' record storage service or for PIs in zones outside of the Central Zone, he/she or designate:

3.1.1. Arranges for appropriate storage of the Research Records.

3.1.2. Records the custodian, the storage location, and the scheduled destruction date of all retained material for future reference, and provides a copy of this information to the Administrative Assistant, Research Services.

3.1.3. Arranges for appropriate destruction of the records at the end of the applicable retention period.

REFERENCES

Health Canada. (2017). *Good Clinical Practice: Consolidated Guideline, International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use – Topic E6*. Retrieved August 17, 2017 from https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/efficacy/good-clinical-practice-consolidated-guideline-topic.html.

Health Canada. Health Products and Food Branch. (2006). *Guidance for Records Related to Clinical Trials, Guide 0068*. Retrieved August 17, 2017 from https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/gui_68-eng.pdf.

RELATED DOCUMENTS

Policies

NSHA Retention of Records is pending. Until such time that the policy is published, please refer to your applicable policy:

CBDHA 3-35 Retention of Records

CDHA CH 07-055 Retention of Records

CDHA RS 01-011 Retention of Research Records

CEHHA 114-006 Retention of Records

CHA Management of Secured Health Records

GASHA 1-35 Retention of Records

SSH HE-190-101 Records Retention

PCHA 12-r-30 Retention of Records

SWH 407.0 Document Retention

Forms

Central Zone:
Sign-Out Sheet for Research Records
Memorandum of Transfer to and Receipt of Research Records by Research Services

Brochures

Records Management Guide for Research Records (contains research records retention schedules)

Central Zone:
So you want to store some research records? Here's how.

Other

- Research Records Storage Box Label
- Storage Box Content List

Appendicies

Appendix A

Replacing the Following District Health Authority Policies/Version History

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Appendix A – Definitions

Research Study	Any study that has been approved by the Nova Scotia Health Authority Research Ethics Board.
Research Records	Research Study-related information received or generated during the course of the research. Media include but are not limited to: handwriting; typing; film; microfilm; photocopies; microfiche; optical disks; and computer disks.
Principal Investigator (PI)	The person responsible for the conduct of a Research Study at the Nova Scotia Health Authority and listed as the PI with the Nova Scotia Health Authority Research Ethics Board.

District Health Authority/IWK Policies Being Replaced

CDHA RS 01-011Retention of Research Records

Version History

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
New to NSHA 2017-09-15	