



Notes:

- 1) All **forms and guides** mentioned in this booklet can be found at <http://www.cdha.nshealth.ca/discovery-innovation/services-researchers/research-records-management>. Always use these forms and guides as they will be the most recent versions.
- 2) The **records retention schedules** contained in this guide apply to **all research records within NSHA**.
- 3) Records storage processes outlined in this guide are intended for **Central Zone** researchers. **Researchers within other NSHA zones** are encouraged to contact Research Services for guidance with their research records. If you have any questions regarding your research records, please contact michelle.rodén@nshealth.ca 902-473-7906

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The role of records

Research records are essential in documenting studies using drug/natural health products or non-interventional studies.

Comprehensive, complete and accurate records:

- meet the stringent regulatory requirements
- fulfill agreements between investigators and sponsors
- demonstrate good research practices and strengthen the reliability of the research as scientific evidence
- safeguard researchers and institutions from allegations of research misconduct or failure to protect personal information
- demonstrate effective stewardship of resources to auditors and to research sponsors
- protect individual and institutional intellectual property rights
- demonstrate compliance with legislation, regulations and other requirements¹

Records take many formats: paper, film, audio tapes, data sets, photographs, videos, diskettes, etc. During the life cycle of a record, it is created and distributed, serves a useful purpose, is stored for further reference, is stored offsite when reference rates drop and usually is destroyed at the end of an identified period, based on its legal, fiscal and administrative values.

There are federal government regulatory guidelines that specify retention periods for clinical trial research records. In some research studies, retention periods may also be specified by the sponsor. Records will be kept for the longest period required.

Institutional Policy Requirements

Policy RS 01-011 *Retention of Research Records*, Nova Scotia Health Authority Research Manual, outlines the general requirements of the institution for the retention and storage of research records. The booklet

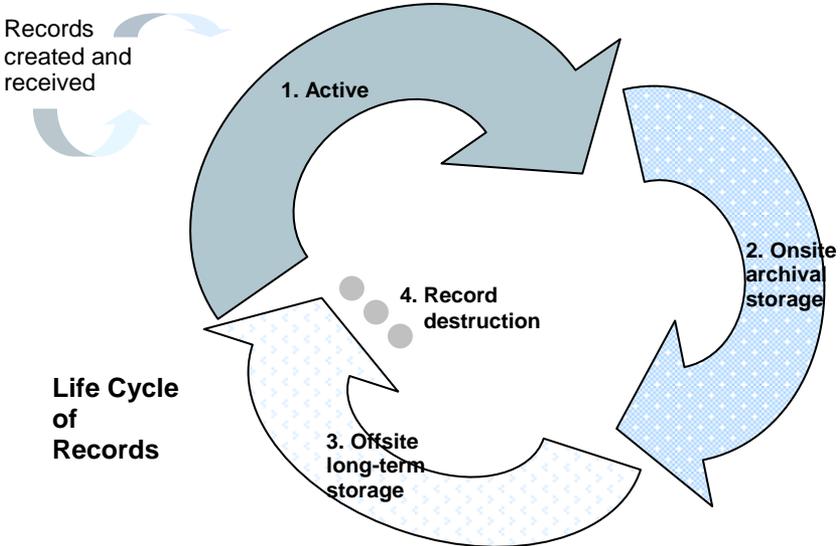
¹ Some points based on JISC InfoNet HEI Records Management Guidance on Managing Research Records

you are now reading supplements the institutional policy with additional information and detailed processes about research records management

How to manage a record's life cycle

A records retention schedule is the document used to outline and manage a record's life cycle. It identifies:

- a. the record's function (e.g., a drug trial record)
- b. active life in the research team's location
- c. the trigger (i.e., study has closed or terminated) for transferring the record to Research Services' onsite storage area
- d. the length of time the record is kept in this area
- e. the length of time the record is retained in offsite storage
- f. the destruction method (i.e., shredding)



The diagram above shows the life cycle of a record from creation to destruction. On rare occasions a record will not be destroyed because it will be preserved permanently – these records contain policies, major corporate decisions and other information deemed to have historical value. These archival records account for approximately two-to-three percent of the information created/received by an organization.

Two main types of records

All records fall into two main types: operational and administrative. In the research world, administrative records (e.g., a supply purchase record) are created to provide the environment and tools necessary for a study to take place. Operational records (e.g., study protocols) are directly related to the study itself. Here are examples of study records:

- Investigator's Brochures and / or product monographs and updates signed protocol and amendments, if any
- sample case report form (CRF) and subject diaries, with any revisions
- copies of signed, dated, completed CRFs and documentation of CRF corrections
- signed informed consent forms and any revisions
- any other written information provided to subjects
- advertisements for subject recruitment
- signed agreements between involved parties
- Research Ethics Board (REB) membership lists
- All correspondence with the REB, interim and final reports, and dated, documented REB approvals
- Health Canada authorization of the protocol and any amendments
- curriculum vitae and/or other documents evidencing qualifications of PI and sub-investigators
- normal values / ranges, certifications / accreditations, quality control assessments / validations for all medical / laboratory / technical procedures / tests included in the protocol
- sample of labels attached to investigational product containers
- instructions for handling investigational products and study-related materials (if not included in protocol or Investigator's Brochures)
- shipping records for investigational products and study-related materials
- decoding procedures for blinded trials
- investigational product accountability at the site
- documentation of investigational product destruction, if product destroyed at the site
- sponsor's trial initiation monitoring report
- relevant communication with the sponsor's representatives (e.g. letters, notes of meetings and telephone calls)
- source documents (to include original documents related to the study, to medical treatment, and history of subject)
- notification by originating investigator to sponsor of serious adverse events and related reports
- notification by investigator to REB (and, where applicable, to regulatory authority) of unexpected serious adverse drug reactions and other safety information
- notification by sponsor to investigators of safety information

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- subject screening log
- subject identification code list
- subject enrollment log
- delegation logs and signature sheets
- records of retained body fluids / tissue samples, if any
- final report to the regulatory authority, if applicable
- clinical study report, if applicable
- Pharmacy logs

Administrative records

The purpose of this booklet is to talk about operational research records; however, it is useful to know that other records are managed with institution-wide retention schedules. (See *CH 100-055 Administrative Manual Retention of Records*.) Administrative records are common to all organizations and fall into several categories: human resources, finance, materiel management and information management. With the exception of personnel and financial records, most administrative information has a short life cycle. Retention periods for personnel and financial records are set by NSHA Departments of Finance and People Services. These departments are the Offices of Primary Responsibility for finance and personnel records. They are responsible for retaining the records for their full life cycle to ensure that all audit, legal and fiscal requirements are met.

Administrative records must not be intermingled and stored with operational records. They must be kept separate.

Research records

The following pages contain records retention schedules to manage the life cycle of research records. Each schedule contains the following:

- title of the record group
- brief description of the purpose of the records
- trigger to transfer records out of the research team's office
- length of time to keep the records stored on-site
- length of time to keep the records stored off-site
- method of disposition (destruction)
- other useful tips
- explanation of abbreviations

The following two records retention schedules outline the life cycle of records for:

Schedule 1: drug and natural health products trials (normally 25 years)

Schedule 2: non-interventional studies and clinical trials that do not involve drugs or natural health products (normally 7 years)

NSHA Research Records Retention Schedule 1

Drug and Natural Health Products Trials				
<p>Contains all records for clinical trials for drugs, natural health products and other trials for medical devices, surgical technique.</p> <p><i>For a complete listing of the types of documents created/received during a trial, check the FDA ICH CGP Section 8.</i></p> <p>http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf</p>				
	On Site	On-Site Storage	Off Site	Disposition
<i>(Name of Study)</i> Clinical Trial Records*	SC/ST	At least 5 yr	Up to 20 yr	S/I
<p>*A 25-year retention period is required by Health Canada. If your sponsor/funder requires a longer retention period, use the number they specify.</p> <p>NOTES:</p> <p>If an employee leaves the study team, ensure a copy of his/her training records remain with the study files.</p> <p>If electronic records are stored separately, note this information and include it with the paper study records.</p> <p>Electronic records may need to be stored in hard copy or a plan in place for future access and retrieval through migration to current software applications.</p> <p>E-mails containing significant information should be printed and retained in paper copy.</p> <p>Related records held by the lab, pharmacy or radiology need to be retained.</p>				
<p>S/I= Shred/Incinerate SC = Study closed ST = Study terminated</p>				

NSHA Research Records Retention Schedule 2

Non-Interventional Studies and Clinical Trials that do not Involve Drugs or Natural Health Products

Contains records for studies that have no investigational product.

	On Site	On-Site Storage	Off Site	Disposition
(Name of Study) Non-Interventional Studies	SC/ST	7 yr		S/I

NOTES:

If an employee leaves the study team, ensure a copy of his/her training records remain with the study files.

If electronic records are stored separately, note this information and include it with the paper study records.

Electronic records may need to be stored in hard copy or a plan in place for future access and retrieval through migration to current software applications.

E-mails containing significant information should be printed and retained in paper copy.

S/I= Shred/Incinerate

SC = Study closed

ST = Study terminated

Stage one of the record life cycle – active life

Main categories of research records

Research records fall into two main categories:

- drug and natural health products trials
- non-interventional studies and clinical trials that do not involve drugs or natural health products study records (other studies)

Government regulations require drug and natural health products trial records to be retained for 25 years. Other studies do not have regulated retention requirements and seven years is the recommended retention period; although this may be superseded by the terms of an agreement where a funding agency requires a longer retention period.

Responsibility for research records

The Principal Investigator (PI) is responsible for the accuracy, completeness and security of the records while the trial is being conducted and for meeting the required government-regulated retention period. It is important to ensure that records are stored in adequate space with security measures in place to protect the confidentiality of the records and in a stable, clean environment to protect the records themselves from damage due to water, dirt and fluctuating temperatures.

Confidentiality issues

The protection of private medical information is legislated. Research records must be treated as carefully as all other patient records. This means storing records in office cabinets that can be locked; not leaving the office door open with records easily accessible; and never leaving boxes of records in hallways or insecure areas for any reason.

Access issues

Confidentiality of records is balanced by the patient's right to access. Provincial legislation outlines the requirements for both confidentiality and access to patient records. The Research Ethics Board also reviews record confidentiality and access at the beginning of the research project and at its closure. (See Section F of the *Ethics Approval and Submission Form* and Section F of the *Study Closure Reporting Form*).

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Access to records is limited to those persons authorized by the PI, the Department/Division Head, the Research Ethics Board or Research Services staff.

Special Cases

Sometimes a study, even though it has been approved, does not go forward and sign up patients. When no patients have been involved, there are two possible scenarios that could happen:

- A. Drugs are received by the study group, not used, and returned to the sponsor.
- B. No drugs have been received by the study group.

If A is the case, the only record that must be retained for 25 years is the documentation from the sponsor indicating that the drugs have been returned. There is no requirement to keep other records of the study. There are no requirements to keep records if B is the case.

Challenges of electronic records

Access

Technology changes rapidly—providing future access to the electronic records we create today will be a challenge. In 20 years, will you be able to read the Word 3.0 document or query your in-house-developed database? Migration of data to newer versions of software at regular intervals or the transfer of data to more stable formats before storage (e.g., PDF files) should be considered. Some people choose to transfer data to paper but this is a labor intensive solution, not to mention the associated costs for long-term storage in space and fees.

Confidentiality

Electronic records must be protected with passwords and other security measures. Be aware that laptops or diskettes containing research information must be protected from unauthorized access. If your laptop was stolen, would it contain confidential patient information? Would you be able to recreate this information?

Backup

If your system crashes, are you protected against loss? How much information would you have to re-create? Could you obtain all the information again? To prevent loss, save your electronic records to a NSHA system drive which is backed up regularly. (Note that no backup is provided for C drives.) If your computer is not backed up by NSHA or if you have no local backup procedures in place, your data is at high risk of loss.

E-mails

E-mails often contain significant information about decisions that have been made or directions that have been given. These e-mails should be printed off and incorporated with paper records or stored on a diskette. When you are documenting an e-mail trail, print the last in a sequence of back-and-forth communications. Do not print each e-mail separately, but print the final e-mail which contains messages that were sent and received previously.

Stage two of the record life cycle—on-site storage

*NOTE 1: Records storage processes outlined in this guide are intended for **Central Zone** researchers. **Researchers within other NSHA zones** are encouraged to contact Research Services for guidance with their research records. **All NSHA research records** fall under the NSHA Research Records Retention Schedule on pages 9 and 10. If you have any questions regarding your research records, please contact michelle.roden@nshealth.ca 902-473-7906*

NOTE: The study PI must ensure that storage is either at NSHA or at a facility leased by NSHA. For records not stored by Research Services, the PI is responsible for providing Research Services with the name of the custodian, physical location and the scheduled destruction date. This information helps maintain continuity of information regarding research record and the management of their life cycle.

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Transferring your records to the Research Services storage area occurs when a study closes. How quickly you do this will depend on how often you need to access the records and space limitations in your area. Since this is a process you do infrequently, it is easy to forget how. Read the on the following pages of this booklet and, if you are still unsure, please ask the Administrative Assistant (473-7906) for assistance.

Records Storage Supplies

Materials:

1. Records storage boxes: Grand & Toy storage boxes (item No. 99801) or size 12x15x10 bankers box. No other boxes (e.g., supply boxes or plastic bins) or larger size boxes will be accepted.
2. Adhesive box label sleeves (available from Research Services)
3. File folders, plastic cable ties (available from Research Services)

Forms:

Available at: <http://www.cdha.nshealth.ca/discovery-innovation/documents>

1. *Research Records Storage Box Label*
2. *Storage Box Content List*
3. *Memorandum of Transfer and Receipt of Research Study Records*

Time:

Several hours to organize the boxes you intend to store

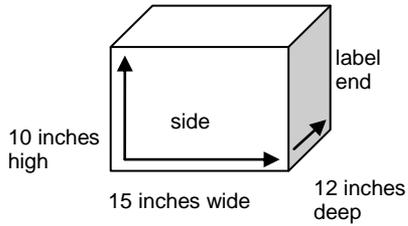
Knowledge:

Study retention requirements that apply to the records:

1. 7 Years: Non-Interventional Studies and Clinical Trials that do not Involve Drugs or Natural Health Products or
2. 25 Years Drug and Natural Health Products Trials or
3. another retention period required for a specific reason

Records Storage Box

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Preparing Records for Storage

Paper Records

Review the files you plan to transfer. **Only research study materials** may be stored—**no** non-study documents.

1. Must do's:
 - a. Remove all binders and insert plastic cable ties through the holes.
 - b. Remove all hanging file holders and place records in file folders.
 - c. Remove all blank forms, extra copies of brochures, etc.
 - d. Remove all duplicates, including copies of originals held by others.
 - e. Remove all devices, equipment and non-record items.
 - f. Place a reasonable number of files in each box – it must not be too heavy!

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- g. Place files upright, not flat.

	Research Records Storage Box Label (manual)	Research Services Use Only
Zone/Department/Division /Service: _____		
Principal Investigator: _____		
Site Investigator (if applicable): _____		
Contact Person for this Study: _____		
Study Title: _____		
Sponsor: _____		
NSHA REB No.: _____	Protocol No.: _____	
Year of Study Closure: _____ <small>(yyyy)</small>	Date boxed for storage _____ <small>(yyyy/mm/dd)</small>	
Retention Period: <input type="checkbox"/> 25 years – Drug and Natural Health Products Trials <input type="checkbox"/> 7 years – Non-Interventional Studies and Clinical Trials that do not Involve Drugs or Natural Health Products <input type="checkbox"/> Other – Specify number of years _____		
Year of Destruction: _____	Boxed by _____	
<small>Calculate: year of study closure + retention period (e.g., 2002+25=2027 or 2011+7=2018)</small>		<small>(Print Name)</small>
Box _____ of _____		
<small>Revised May 2015</small>		

2. Fill in one *Research Records Storage Box Label* for each study. Fill in just the total number of boxes (e.g., Box ____ of 12).
3. Photocopy one label for each box. Then fill in the box number (e.g., Box 1 of 12) on each label.
4. Photocopy the set of completed labels for Research Services' use. Twelve boxes require 12 photocopied labels.
5. Affix a label sleeve (available from Research Services) to the end of each box. Slide a box label into each sleeve.
6. Fill in a *Storage Box Content List* for each study. This is a record of which box contains which document. This will help you when you need to retrieve a document. Keep copies of the list in your office. Do not send these lists to Research Services.
7. Contact the Research Services Administrative Assistant to arrange a time to transfer the boxes to Research Services.

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NEVER UNDER ANY CIRCUMSTANCES LEAVE BOXES UNATTENDED IN HALLWAYS OR UNSECURED AREAS. BOXES CONTAIN CONFIDENTIAL PATIENT INFORMATION AND MUST BE PROTECTED!

8. Complete Part A of the *Memorandum of Transfer and Receipt of Research Study Records* form. E-mail it to Research Services.
9. Transfer the labeled boxes, the Memorandum of Transfer form and the complete photocopied set of box labels to Research Services.
10. Research Services will confirm receipt of your boxes by returning the *Memorandum of Transfer and Receipt of Research Records* with Part B completed.

Electronic Records

1. Review the records to ensure they are complete. If there are e-mails that should be included, print them off and include them. Only print the complete, final threaded version of an e-mail interchange—the one that contains the total exchange of e-mails that have gone back and forth. Are there records at Pharmacy, the lab or radiology that relate to this study? They need to be retained as well.
2. Identify location of electronic data (e.g., sponsor headquarters database). Place this information inside the boxes and keep with your records of transferred boxes for future reference.
3. Label tapes, diskettes and other storage media clearly.
4. Identify software and hardware requirements for accessing data and include that information in the study package.

Do It Right!

Stop before dumping stacks of records into boxes! Set aside the time to organize the records efficiently. Think ahead to identify which records you would be most likely to retrieve and place them together. Organize records in the boxes in a logical manner. Minimize the number of boxes by removing contents from binders, weeding out duplication and by excluding non-record materials. Save storage space and expense by organizing carefully.

NSHA Records Management Guide for Research Records

Purge duplication. Do not keep drafts—only the final copy. Is there a reason to keep different versions of a document? If different versions are retained in the file, identify the final version. Do not keep multiple copies of blank forms, brochures, etc. If you need to keep several versions of brochures or other publications, write on them “superseded by” or other identifying information.

Keep box weight reasonable—18 pounds (8 kg) or less. Remember someone must lift these boxes onto shelving units. Fill boxes so that they are neither packed too tightly (making it difficult to remove contents) or packed too loosely (with contents curled up and fallen over).

Remember that these boxes contain confidential patient information and must be kept in a secure location and never left unattended in hallways or open areas. Protect patient information at all times.

Records Retrieval

Note: The PI has the authority to request record retrieval. The PI may designate a study team member by written note or e-mail to retrieve records on his/her behalf.

On-site records

1. Use your Records Storage Box checklist to help you identify the box you want. Set up a time with the Research Services Administrative Assistant (AA) to retrieve the box you need. The AA will accompany you to assist you to locate the box.
2. If you remove the box from the storage room or remove records from the box, you and the AA must complete a *Box Sign-Out Sheet*. This shows that research records have been removed from the Research Services storage area. If a box is removed, the space that box occupied is reserved for the return of the box when you are finished with it.

Off-site records

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1. Speak with the AA and specify which box(es) you need. The box(es) will be requested for you and there will be a charge to you, based on service level.
2. A fee will be charged to you to retrieve a box from the service provider. Retrievals are available for: next day, half day or rush (the quicker the delivery, the more expensive the fee). Speak with the Administrative Assistant about costs and retrieval times. Retrieval requests require: department name, physical location where the boxes are to be delivered, protocol number/study title, date of study closure and box number (i.e., Study XYZ closed in 2005, box 3 of 10).

Stage three of the record life cycle—off-site storage

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From on-site to off-site

Research Services stores records in the Centre for Clinical Research for several years, then transfers them to a secure offsite storage facility. The PI is informed by Research Services when transfer offsite will occur. The PI is still the owner of the records but has designated the responsibility for physically storing the records to Research Services. The cost of storage is paid by Research Services. Cost of retrievals is borne by the study team.

Drug and natural health products trial records are retained for 25 years after the study closes. The retention date and, ultimately, date of destruction can be calculated by adding 25 years to the study end date (date of study completion at this site; i.e., the date all study activities were completed). For studies ending in 2010, for example, date of destruction will be 2035. This information appears on the record storage box label.

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Retrieval rate must also be taken into consideration and there may be the rare occasion that records transfer to off-site storage will be delayed. If a study has closed and there is still a retrieval rate of once a month or more, the records are not yet ready for transfer to off-site storage.

When records are due to be transferred to an off-site storage facility, a memo will be sent to the PI:

Research Services assigns each box of records a unique number which is used by the service provider to identify the box in its offsite storage location. Records retrieval from offsite is arranged with the Research Services Administrative Assistant and must be authorized by the PI. Only Research Services staff are able to request records from the service provider. In order to protect the confidentiality of the records, retrieval is provided only at the request of: the PI, Department/Division Head, Research Ethics Board or Research Services staff.

The end of the records life cycle— destruction

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Records are due to be destroyed when their retention period is complete. At least six weeks before destruction of the records is scheduled, Research Services will inform the PI, or the Department/Division Head (if the PI is no longer available). The research study sponsor is informed at this time to ensure they have no further need of the records. The sample form letter below could be used to do this:

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Letter Informing Sponsor of Destruction of Research
Study Records

From: P.I. or Department/Division Head or Director of
Research Services

Address

Date:

To: Sponsor

Re: Study Title: xxxxx

The records of the study noted above have been retained for 25 years, as required by federal government regulations. They are now due to be destroyed. If I do not hear any objection to this destruction from you, these records will be destroyed on (current date plus four weeks).

Yours very truly,

Signature of PI or Department/Division Head
e-mail address; phone number

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If there is a reason to postpone destruction, the PI or Department/Division Head must inform Research Services as soon as possible of this (at least two weeks prior to the date scheduled for destruction). Arrangements can then be made to extend record retention.

Paper records are destroyed by shredding in a secure facility. Other media is pulverized and then incinerated. This ensures confidentiality and fulfills the final intent of the records schedule which specifies the date and method of record destruction.

Records Destruction Authorization Form

The completed destruction form contains the signature of the PI or Department/Division Head, indicating that the person with responsibility for the records has approved their destruction. This form is retained by Research Services to prove that destruction has been approved and completed.

Research Records Storage Management System

The Research Services on-site storage area contains over 2000 boxes of records. A new records storage database will help control and organize this storage area. to:

- provide better and more efficient control of physical box location in the storage area
- allow the printing of reports to identify:
 - the number, location and content of all boxes from a particular PI, department, study or research team
 - which boxes are due to be moved to offsite storage

These examples are a few of the anticipated uses of employing a database to track boxes. This information will be useful from both an administrative and user perspective.

Glossary

Administrative records: records common to all organizations, including human resources and financial records. These records support the structure that allows research to occur. Usually these records have short retention periods and are managed by their office of primary responsibility; e.g., Finance or People Services. *See operational records.*

Disposition: the method by which a record is destroyed; e.g., recycling, shredding, incineration

Life cycle: the life stages of a record from its creation to its destruction

Operational Records: records that are received or created in the conduct of a particular mandate such as a drug study Examples: study protocol, study closure form. These records have long retention periods to meet their legal, regulatory and sponsor requirements. *See administrative records.*

Records Retention: the safeguarding of records for a specified time to fulfill administrative, legal, operational and fiscal requirements.

Records retention schedule: the plan for managing the life of a record, identifying how long it is to be retained and how it is to be destroyed at the end of its life.

Retention Period: the length of time records are required to be kept

Storage Location Box Number: The number identifying the physical location of a box in the Research Services on-site storage area. This number is assigned by Research Services and appears in the records storage database as the unique location identifier for each box stored on-site.

Study end date: date of study completion at this site; i.e., the date all study activities were completed.



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<http://www.cdha.nshealth.ca/discovery-innovation>