Research Road Map

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* *Acknowledgement to the Nova Scotia Health Authority for sharing their archiving information that was used to help create this roadmap.*

Archiving Research Files

It is the responsibility of the Principal Investigator (PI) of a research study to arrange for the archiving of their research records. On completion of a research study all essential documents need to be sealed in boxes in preparation for archiving. All research records are required to be archived in a secure and safe environment which restricts access to authorized research personnel only. The location of these documents and date of destruction must be known to the PI, Institution (if PI no longer located at Institution) and Sponsor/Clinical Research Organization (CRO). Clinical trial records must remain accessible and available to any relevant regulatory and inspection authority(ies) (i.e. Health Canada, FDA), local/central research ethics board(s) (REB), and Sponsors/CROs.

WHAT TO ARCHIVE?

International Council for Harmonization (ICH E6 R2) Good Clinical Practice (GCP) Guidelines (ICH-GCP E6 R2 Section 8) contains a list of essential documents for the conduct of a clinical trial. Essential documents should be kept for the entire retention period and in their original medium (e.g. paper, electronic, microfilm, tracings, etc.). Transfer of essential documents from their original medium to a secondary medium may be acceptable, preferably at the completion of a trial, and only if: the corrections to the original data can be clearly captured in the secondary medium, the person that performs the task of transferring from the original to the secondary medium attest (sign and date an attestation), that the secondary documents are true copies of their respective primary documents, and the transfer process has been fully validated. Evidence of validation should be available for inspection. It is important to verify with your local/central REB and Sponsors/CROs if transferring research records from an original medium to a secondary medium is acceptable.
Here are examples of study records (essential documents) that must be archived:

- signed protocol and amendments, if any;
- investigator brochure or product monograph;
- sample case report form (CRF), with any revisions;
- copies of signed, dated, completed CRFs and documentation of CRF corrections;
- signed informed consent forms and signed revised consent forms;
- any written information provided to participants;
- advertisements for participant recruitment;
- signed agreements and amendments between involved parties;
- Research Ethics Board (REB) membership lists;
- all correspondence with the REB, interim and final reports, and dated, documented REB approvals and REB amendment approvals;
- Health Canada/FDA authorization of the protocol and any amendments;
- curriculum vitae and/or other documents evidencing qualifications of PI and sub-investigators;
- normal lab values/ranges, lab certifications/accreditations, and quality control assessments/validations for all medical/laboratory equipment, technical procedures/ tests included in the protocol or amended 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 brochure or product monograph);
- 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 site);
- sponsor's trial initiation monitoring report;
- relevant communication with the sponsor's representatives (e.g. letters, notes of meetings, emails, and telephone calls);
- source documents (includes original documents related to the study, medical treatment(s), and history of participant), for example:
    - Hospital records
    - Clinical and office charts
    - Laboratory notes and reports
    - Memoranda
    - Participant diaries or evaluation checklists
    - Recorded data from automated equipment
    - Certified copies or transcriptions
    - Microfiches and microfilm
    - Photographic negatives
    - Magnetic media
    - X-rays
    - Participant files
    - Other medico-technical records
- notification by PI to Sponsor/CRO of serious adverse events and related reports;
- notification by PI to REB (and, where applicable, to regulatory authority(ies)) of unexpected serious adverse drug reactions and other safety information;
- notification by Sponsor to PI of safety information;
- participant screening logs;
- participant identification code list;
- participant enrollment logs;
- delegation logs and signature sheets;
- research personnel training logs;
- records of retained and shipped body fluids/tissue samples, if any;
- final report to the REB and/or regulatory authority(ies), if applicable;
- clinical study report, if applicable;
- temperature logs for drug storage and/or fridges/freezers;
- pharmacy dispensing/accountability/storage logs.

***In order to ensure that all portions of electronic and/or paper Hospital medical records for participants*

are kept for 25 years for clinical drug trials, the PI (or task delegated to research personnel) needs to notify the Hospital's (KHSC and/or PC) Medical Records Department in order to work out a process for retention.

Special Cases

Sometimes a clinical drug trial, even though it has been approved by local/central REB, does not go forward and screen research participants. When no research participants have been involved, there are two possible scenarios that could happen:

Scenario A: Study drugs are received by the PI from the Sponsor/CRO, not used, and are destroyed by PI at the request of the Sponsor/CRO or returned to the Sponsor/CRO.

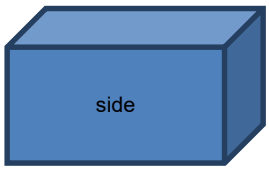
Scenario B: No study drugs have been received by the PI from the Sponsor/CRO.

If Scenario A occurs, the only research record that must be retained for 25 years is the documentation from the Sponsor/CRO indicating that the drugs have been destroyed or returned. There is no requirement to keep any other research records for the clinical drug trial. If Scenario B occurs, there are no requirements to keep any research records.

WHEN TO ARCHIVE?

Essential documents need to be archived once the research study is completed (e.g., the clinical drug trial has undergone a final closeout visit by the Sponsor/CRO, the closeout report issued by the Sponsor/CRO, and the final report written is received by PI). The completion of a clinical drug trial shall be determined by the Sponsor/CRO and may vary among studies. For investigator-initiated clinical trials, the PI is the Sponsor. The date of the completion of any research study should be documented.

HOW TO ARCHIVE?



label side

What you need:

1. Archival banker boxes: purchased storage boxes: size 1.2 cubic ft. standard banker box. Please note that off site storage facilities do not accept other boxes (e.g. supply boxes, plastic bins, copy paper boxes, or larger size boxes).The off site storage facility will not accept torn or crushed banker boxes. Any damaged boxes will require the material to be rehoused by the offsite facility and done so at the expense of the PI.

2. Box label: *Research Records Storage Box Label*.*

3. File folders, plastic cable ties or binder rings (suggested for keeping documents together). Elastic bands disintegrate over time.

4. Several hours to organize the boxes you intend to store.

5. To know the study retention requirements:

   a) Non-Interventional Clinical Studies and Clinical Trials that **do not** involve drugs or natural health products: ~***2-10 years*** depending on funding agency and/or local/central REB requirements.
   b) Clinical Drug Trials and Natural Health Products Trials: ***15 years.***
   c) Another retention period required for a specific reason.

* *Contact* **kghri@kingstonhsc.ca** *for templates.*

Steps to prepare records for storage:

Paper Records

1. a) Remove all binder contents and insert plastic cable ties or binder rings (if being used) through the paper holes.

   b) Remove all hanging file holders and place research records in file folders.

   c) Remove all blank forms, extra copies of brochures, etc.

   d) Remove all duplicates.

   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 (no more than 40 lbs)! And partially filled boxes will be charged the price of an entire box.

   g) Place files upright, not flat (for ease of locating items if retrieval is required).

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, Box 2 of 12, etc.) on each label.

4. Photocopy the set of completed labels for your records. Twelve boxes require 12 photocopied labels.

5. Affix a label sleeve to the end of each box (courier sleeves work great!). Slide a box label into each sleeve. Remote storage facilities often require their own labeling in addition to any labeling suggested here. (e.g., Iron Mountain has its barcode labels).

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 a document. Keep copies of the list in your office. If this is done successfully, when records do need to be pulled it can be done with precision and save costs. Poor record keeping of box contents leads to higher costs if or when records need to be retrieved.

7. PI should identify and document which research personnel has the authority to retrieve the research records from the archive/storage facility.

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Electronic Records

1. Label tapes, diskettes and other storage media clearly before storing in boxes.

2. Identify software requirements to access the information and include this information with the storage media.

3. Consider the following:

   Access: Technology changes rapidly—providing future access to the electronic records we create today will be a challenge. 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.

   Confidentiality: Electronic records must be protected with passwords and other encrypted security measures. Be aware that laptops or diskettes containing research records must be protected from unauthorized access. It is essential that you ensure that the passwords are kept somewhere that is discoverable by the Department or relevant Research Unit should the PI/Coordinator leave the Institution and access is required by the Sponsor or Regulatory bodies.

   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/save the last in a sequence of back-and-forth communications. Do not print/save each e-mail separately, but print/save the final e-mail which contains messages that were sent and received previously.

Electronic Data Capture Systems (EDC)

Tips to consider:

1. The database must be archived to meet local, national, and international requirements and may entail storing of the software version, including any software patches and updates used in the software version and all hardware components to resurrect the database in its original state.

2. Export the metadata, clinical data, code lists, coding dictionaries, audit trails, edit check documentation, discrepancy management documentation, and queries to long-term storage media in an open format (such as CSV files, XML, SAS Transport files, or PDF) and ensure the media are labeled appropriately, including archive date

and how long the media must be maintained. Ensure test data in any test databases are also archived.

3. Record the hardware and software used for the study, including the specific version(s). This may be recorded in the study database manual or Data Management Plan.

4. Record the user history, including the user listings, all access rights or levels and any changes and the associated authorization dates.
5. Remove all necessary database access except for an administrator account that controls all user accounts and accessibility to the database.

6. Ensure that the archived database and documentation are kept in a secure environment and that adequate backup copies have been performed.

7. The media storage device used to archive the database must be replicated to ensure that there is a working, backup copy in the event the original is damaged or unobtainable.

8. Establish a test schedule with regular timeframe intervals, such as every five years, to test that the archived database is retrievable and will load and run.

NEVER UNDER ANY CIRCUMSTANCES LEAVE RESEARCH BOXES UNATTENDED IN HALLWAYS OR UNSECURED AREAS. RESEARCH BOXES CONTAIN CONFIDENTIAL PARTICIPANT INFORMATION AND MUST BE PROTECTED AT ALL TIMES.

HOW LONG TO ARCHIVE?

Clinical Drug Trials and Natural Health Products (NHP) Trials: Health Canada has issued the Notice: Period Reduced for Keeping Clinical Trial Records for Drugs and Natural Health Products. They are reducing the retention period for clinical trial records for drugs and natural health products from 25 years to 15 years under the *Food and Drug Regulations and Natural Health Products Regulations*. This change is effective February 11, 2022:
https://www.canada.ca/en/health-canada/services/clinical-trials/notice-period-reduced-keeping-records-drugs-natural-health-products.html
The requirement to keep records for 15 years applies to:

- clinical trials of all drugs and natural health products

This retention period will allow for research participant follow-up throughout the subsequent stages of drug development, assessment and marketing as well as provide the ability to assess the impact on second generation. The starting time to calculate the retention time is the date when a research record is created. For example, when an informed consent is signed, the date of the signature by the research participant is the starting date. In practice, it may be easier to calculate the starting date for research record retention, as the date of completion or termination of the clinical drug or NHP trial.

For trials not covered by Division 5 regulations, study files may be destroyed after the required document retention period prescribed by ICH GCP and federal, provincial, and local regulations and policies. The time frame is dependent on the research study type, funding agency conditions, and local/central REB and governing oversight authority

requirements. Funding agencies such as CIHR require grant recipients to retain original data sets for a minimum of five years (or longer if other policies apply) after the end of the grant. The Queen's HSREB requires that research records are retained for a minimum of 5 years from the last date of publication or other form of presentation or longer if mandated by a legal requirement or an applicable funding or oversight agency. Remember: each funding agency/oversight authority will have their own guidelines, so PIs are encouraged to check with them and keep their research data in the original medium (or secondary medium if approved) for the greatest time period.

WHERE TO ARCHIVE?

PIs are responsible for archiving all research records. The Hospitals do not have the space or resources to assume this responsibility from the PIs. PIs have two options for storing their research records:

Short term onsite storage: Research records can be stored in a PI's dedicated research office or laboratory temporarily (until long term storage is set up) as long as the location is secured (e.g. locked room or locked cupboard). PIs need to consider fire and water protection (e.g. sprinklers), humidity and temperature conditions, pests, etc. when choosing the appropriate onsite storage area. Access to onsite storage must be restricted to authorized research personnel only.

Offsite storage: The research records will need to be transferred to a secure offsite storage facility for long term storage as required by KGHRI Clinical Record Long Storage Policy. The cost of offsite storage is the responsibility of the PI. The recommended storage facility is:

Iron Mountain Canada
(http://www.ironmountain.ca/en/Services/Records-Management-And-Storage/Records-Storage.aspx)
Iron Mountain Canada
650 Dalton Avenue, Kingston, Ontario K7M 8N7
(613)531-4222

Contact Queen's Record Manager at Queen's Record Management and Privacy Office 613-533-6095 T https://www.queensu.ca/accessandprivacy/. This initial contact can answer questions and prevent potential errors and work that can result if done incorrectly.

DESTRUCTION OF RESEARCH RECORDS

Research records are due to be destroyed when their retention period is completed. For clinical drug or natural health product trials, at least 4 weeks before the due date of destruction of the research records occurs, the PI (or delegated research personnel or the Department/Division Head if the PI is no longer at the Institution) must inform the Sponsor/CRO through a Notification Letter* to ensure that the Sponsor/CRO has no

further need of the research records to be retained longer (at the expense of Sponsor/CRO) and the Sponsor/CRO grants permission for you to destroy the records.

Written confirmation from the Sponsor/CRO to destroy the records is required as per SOP and documentation of destruction to the Sponsor. If research records are onsite, PIs can contact the Hospital's (KHSC and/or PC) Environmental Services Department to have the research records removed and destroyed as per Hospital policy related to confidential documents. PIs will need to provide the Hospital's Environmental Services Department with the number of banker boxes to destroy. The Hospital's Environmental Services Department will determine whether to drop off to your research area a locked big blue bin for you to empty your banker boxes into or request that you shred the documents and then they will take away the shredded research records as per Hospital policy related to confidential documents. Please contact Housekeeping at extension 7250.

If the records are offsite at a professional storage facility (e.g., Iron Mountain), it is the responsibility of the person that has access to the records to run reports to determine when records are eligible for destruction. Otherwise, the facility (Iron Mountain) will retain them indefinitely and charge accordingly. When the date has arrived to destroy records, destruction requests must be made through Queen's Records Management and Privacy Office.

It is recommended to set a calendar reminder to run a report once or twice yearly to identify what and when records are eligible for destruction. First step would be to run a report from Iron Mountain to identify the records, second step would be to contact the Records Manager at Queen's University to facilitate the disposal. The Records Manager will liaise with Iron Mountain and provide documentation of disposal.

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