ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates

Tool Time

Archiving of Clinical Health Research Records Guidance Document

Clinical Research Stage:

Concept

Development

Feasibility

Project in Setup

Active Study

Close-out

ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

Alberta SPOR Support Unit

College of Physicians & Surgeons

Covenant Health

University of Alberta

University of Calgary

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It can be confusing to know who is responsible, how, and length of time to keep clinical health research records. This can be compounded by potentially having a hybrid of both paper and electronic media. An archiving strategy should be considered at the beginning, rather than the end of a clinical health research project life cycle so associated costs, staff time, processes, etc. may be built into the study budget. All records, including electronic records, need to be accessible during the entire archival period, thus considerations must be made on the type of device and formatting of data to maintain accessibility. Ultimately, study archiving is the responsibility of the PI and/or institution conducting the study.

The *Archiving of Clinical Health Research Records Guidance Document* will provide information on the archiving and storage of documents and data that are created and gathered as part of clinical health research. This guidance refers to local policies and institutional requirements in Alberta along with requirements of Health Information Act (HIA), Canadian Institution of Health Research (CIHR) and Health Canada.

WHAT ARE THE RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR AND/OR INSTITUTION?

For *Sponsor Initiated Studies* the Principal Investigator (PI) is responsible for the conduct of the clinical health research at the site, but is not the sponsor including:

- Storage of essential documents as outlined in Good Clinical Practice (GCP) (ICH Good Clinical Practice R2)[1].
- Management of the research records from study start up to the end of retention period (See Table 1 for retention periods).
- Development of a site specific standard operating procedure (SOP) clearly indicating the site's archiving logistics (including timeframe, location and contact details) and process.
- Obtaining the appropriate research agreements to access, retrieve, and retain the records from a repository owner if maintained externally.
- Protection of the records that ensures the integrity of information (e.g. measures against water, or fire damage).
- Execution of a Clinical Trial Agreement (CTA) that clearly outlines and references the site's record maintenance and retention responsibilities.
- Where possible, consultation with the study sponsor and data custodian should be held prior to the destruction of records created during the conduct of clinical health research studies.

For Investigator Initiated Studies (i.e. a PI who is also a sponsor), A PI who is also a sponsor[2], is additionally responsible for:

- Recording, handling and storing all clinical health research information to allow its complete and accurate reporting, as well as its interpretation and verification.

[1] ICH GCP E6(R2)
[2] Part C, Division 5 of the Food and Drug Regulations [C.05.012] - *Sponsor's Obligations - Records*

Relevant Regulations

[Part C, Division 5 of the Food and Drug Regulations [C.05.012] - *Sponsor's Obligations - Records*]

[ICH Guidance E6(R2): Good Clinical Practice (GCP)]

[Tri-Agency Statement of Principles of Digital Data Management]

Reasonable efforts have been made to ensure accuracy of information and compliance with the regulations however, the ACRC and partner organizations are not responsible for any omissions or errors.

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- Maintaining complete and accurate records to show that the trial/study is conducted in accordance with GCP, Health Information Act, and if applicable, the Health Canada regulations.
- Maintaining complete and accurate records in respect of the use of a drug/device in a clinical trial/study.
- Conducting a clinical trial/research study and overseeing the records archiving process, which includes relaying expectations to third parties including other sites in multi-centre studies.
- Cost of archival.

WHAT SHOULD BE ARCHIVED?

All documents, correspondence, and records created or obtained during the conduct of the study must be archived. Note, copies, drafts or temporary records to not need to be archived. These include all relevant study start-up documents, source documents, all related correspondence, research ethics board records, drug accountability and reconciliation reports, temperature monitoring reports, shipping and receiving documents for all materials, and any audit or monitoring reports. Refer to the below list for **an example** of essential documents required for archival:

- Study-related administrative and regulatory materials:
    a. Protocol, IB, informed consent document (all versions)
    b. Study information given to the participant – diaries, advertisements, etc.
    c. Signed agreements – contracts
    d. Approvals – Health Canada, REB, institutional
    e. Lists – screening, identification, randomization
    f. Delegation log
    g. Study reports – periodic and final
    h. Monitoring reports
    i. Notes to File
- Source documents on participants
    a. Signed informed consent forms, medical records
    b. Participant study charts, tests, reports, diagnostic imaging
    c. Subject diaries, appointment records
    d. Completed case report forms, adverse events
- Pharmacy records of the investigational drug (pharmacy documents may need to be obtained directly from the research pharmacy)
    a. Shipping/receiving,
    b. Dispensing,
    c. Administering,
    d. Drug destruction/return
- Laboratory records (lab documents may need to be obtained directly from the research lab)
    a. Shipping receipts (i.e. samples)
    b. Lab normal(s)
    c. Lab certification(s)
- Administration records – letters, notes of telephone calls
    a. Communications with sponsors
    b. Communications with REBs
    c. Qualifications and evidence of training of staff
- Databases (both administrative and study) are per protocol and sponsor and/or research agreement(s), information must be accessible for the appropriate retention period after the study closes. Therefore, considerations must be made as to how electronic information will be stored early in the study's life cycle.
- The PI should retain a copy of the randomization list, the location of the archives, and the audit reports.
- Contracts – per institutional policies

- REBs – note in file if REB study related material is stored separately
    a. Membership list
    b. Qualifications of members
    c. Minutes of the REB meetings
- Medical records – per institutional policies

Refer to ICH GCP E6(R2)8. for a complete list of essential documents.

WHAT ARE ACCEPTABLE STORAGE MEDIA FOR RESEARCH RECORDS?

- Paper
- Electronic data/records should be collected and stored throughout the research study using software and formats that ensure secure storage, preservation of and access to the data well beyond the duration of the research project[3], conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation)[4].
    a. . Information should be:
        i. protected from unauthorized access
        ii. accessible to authorized individuals throughout the retention period
        iii. in a format that can be readable at any time during the retention period
        iv. protected in case of disasters or accessible in case of data recovery
        v. refer to your local institutional for specific practices
- Audio or visual recordings
- Film

WHAT ARE RESEARCH RECORD RETENTION REQUIRMENTS?

Research record retention periods will vary depending on the research intervention, research purpose and type of records involved, but must be retained for not less than the following (see Table 1).

Researchers are advised to consult with their local REB and department/institution for additional policies and practices regarding the preservation, retention, and protection of research data that must be respected.

Records may need to be retained longer if there are allegations regarding the conduct of the research, such as academic misconduct, conflict of interest or for-cause investigations.

Electronic records should be maintained and retained in accordance with section C.05.012 of the Regulations. Include in the file, any validation of the electronic record systems of clinical study data, which is performed annually or after a major upgrade to confirm that the system's specifications consistently meet regulatory requirements in a consistent manner for the duration of the retention period. (GUI-0100).

At the end of the retention period, records are either:

- Destroyed
- Archived due to permanent value
- Selectively retained

Wherever possible, sponsor must be notified prior to destruction of records.

[3] Tri-Agency Statement of Principles of Digital Data Management
[4] https://ichgcp.net/5-sponsor

WHAT ARE THE STORAGE MATERIAL REQUIREMENTS?

In preparing for archival, study records and materials are to be removed from any binders, placed into file folders or banded with elastics for ease of future document retrieval. These should then be placed into either letter or legal-size bankers' boxes (1.2 cu ft) with lids. A label should be placed on the box indicating study specific identification information (study sponsor, protocol name and number, PI, site number, and specific site information, and list of enclosed contents within each box).

Note: When using a repository, check specific repository for further storage requirements.

WHAT ARE THE STORAGE FACILITY REQUIREMENTS?

- Health Canada requires that records be kept in a specified secure location as referenced within your site's standard operating procedure (SOP).
- Records are ideally stored in a location which can be easily accessed by others as needed during the 25-year retention period.
- Records are to be accessible only delegated personnel.

WHAT ARE THE RETRIEVAL REQUIREMENTS?

- Health Canada or other authorized regulatory authorities (Ie FOIP or PIDEPA) can request records with as little as 24 hours' notice; thus, records need to be readily available and accessible.
- Please check your institutional policy and storage facility for the process.

WHO IS RESPONSIBLE FOR DESTRUCTION OF THE MATERIALS?

- The responsibility for destruction of the materials may vary between institutions.
- Please check your institutional policy and storage facility for the process.

WHO DO I CONTACT FOR MORE INFORMATION?

Institution	**Contact information**
Community-based researchers	acrc@albertainnovates.ca
Alberta Health Services	privacy@albertahealthservices.ca
Tom Baker Cancer Centre	Marilyn.David@albertahealthservices.ca
Cross Cancer Institute	rim@ahs.ca
Covenant Health	research@covenanthealth.ca
University of Alberta	University Records Office
University of Calgary	cccr@ucalgary.ca

APPENDIX:

TABLE 1: Records Retention Periods

	Retention Period	Reference
Clinical Research studies subject to Health Canada regulations	• All clinical trials (defined by Health Canada as an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug) including phase IV trials are subject to **25 years retention.** • The retention period begins on the date of study closure with the REB. The date of study closure is when REB has been notified that the study has closed, and when all follow up of subjects is final and there is not further data analysis involving individually identifiable information.	Health Canada / Health Products and Food Branch Inspectorate *Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects"* (GUI- 0100) Section C.05.012 of the *Food and Drug Regulations* - Division 5 *Drugs for Clinical Trials Involving Human Subjects* Guidance on Medical Device Establishment Licensing (GUI-0016) 9. Maintaining Records Tri-Agency Statement of Principles on Digital Data Management
Clinical Research studies **not** subject to Health Canada regulations	• Studies involving humans but not a drug or medical device (e.g. questionnaires, surveys, exercise studies, behavioral studies, etc.) are to be stored for a different minimum depending on type of record and institutional requirements. • The retention period begins on the date of archival, defined as study close-out. **Institutional Retention Periods** (subject to change): **Alberta Health Services** – 15 years for research administration, 7 years for financial records, 5 years for completed research. **Covenant Health** – 5 years for completed research, 7 years for financial records. **University of Alberta** – 5 years for completed research, subject to conditions. **University of Calgary** – 5 years for completed research or in accordance with the research agreement or funding agency.	**Institutional and Health Canada Record Retention Requirements:** Alberta Health Services – Record Retention for Research and Evaluation Purpose Alberta Health Services – Record Retention Schedule Covenant Health Policy on Records Management University of Alberta - Policy on Record Retention University of Calgary - Record Retention Rule
CIHR funded studies	• Records are to be stored for a **minimum of 5 years** after the end of the CIHR grant **unless applicable to Health Canada regulations then 25 years retention.** • This applies to all data, whether it is published or not.	Tri-Agency Open Access Policy on Publications