STANDARD OPERATING PROCEDURE FOR DATA RETENTION

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<tr>
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Revision Chronology:

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<tr>
<th>Version Number</th>
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<tr>
<td>505.01</td>
<td>17 June 2010</td>
<td>Initial Version</td>
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<tr>
<td>505.02</td>
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Written By: Sandra Blamires | _____________ | ___/___/______ |
Reviewed By: Dan Buchanan | _____________ | ___/___/______ |
Approved By: Grace Parraga | _____________ | ___/___/______ |
1. INTRODUCTION & PURPOSE

Appropriate record retention ensures that information from clinical research will remain secure and that it will still be available in the future for inspection by regulatory authorities. Health Canada requires that the data from clinical trials as well as the essential documents from the trial be retained for a minimum of 25 years.

2. SCOPE

This standard operating procedure (SOP) applies to all clinical data and to essential study files.

3. APPLICABLE REGULATIONS AND GUIDELINES

Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials
FDA Code of Federal Regulations, Title 21
International Conference on Harmonisation; Good Clinical Practice: Consolidated Guidelines
Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans
The University of Western Ontario Health Sciences Research Ethics Board Guidelines
Personal Health Information Protection Act
Personal Information Protection and Electronic Documents Act

4. REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are cross-referenced to this SOP.
This SOP refers to GCP SOP 506 – Information Access Control and Security

5. ATTACHMENTS

A. Record of archived materials

6. RESPONSIBILITY

This SOP applies to the clinical personnel responsible for the archiving of research data and the ongoing retention of archived data.
7. DEFINITIONS

The following definitions apply to this SOP:

**Case Report Form (CRF):** A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each research subject.

**Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

**Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

**Source Data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

**Source Documents:** Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subject’s diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

**Study Closure:** For the purposes of data retention, study closure refers to the date on which the last piece of source data is captured for a research study.

8. PROCESS OVERVIEW

A. Retaining paper source documents and essential study files
B. Retaining electronic source documents
C. Retaining case report forms (CRFs)
9. PROCEDURES

A. Retaining Paper Source Documents and Essential Study Files

1. After study closure, all of the essential documents (including source documents) should be compiled and checked for completeness.

2. Complete a record of archived materials including the following information:
   a. The study name and number
   b. The name of the investigator
   c. The date of archival
   d. The period of retention required
   e. The location of the documents
   f. The number of containers

3. Take measures to prevent accidental or premature destruction of the essential documents.
   a. Clearly identify storage boxes
   b. Store in a locked area

4. Prepare to archive the files according to local policies and, if applicable, the sponsor agreement.

5. At the request of the sponsor, auditor, HSREB, or regulatory authorities direct access to all clinical trial-related records must be made available.

6. According to Health Canada Division 5 regulations, maintain all clinical trial records for a minimum of 25 years from completion of the study.

B. Retaining Electronic Source Documents

1. After study closeout, all of the electronic source documents should be compiled and checked for completeness.

2. Complete a record of archived materials including the following information:
   a. The study name and number
   b. The name of the investigator
   c. The date of archival
   d. The period of retention required
   e. The location of the documents (physical or on a network, as applicable)
   f. The date the data was written to the current storage device
   g. The storage format of the documents (type of storage device)
   h. The number of storage devices, if applicable

3. Electronic source documents associated with a clinical trial must be maintained in a format that makes them accessible for the duration of the prescribed archival time.

4. Electronic storage methods are constantly evolving, and current methods of data storage do not maintain the integrity of the data over long periods of static storage. Therefore electronic data must be reviewed every 5 years.
during the retention period to maintain the integrity of the data and ensure its accessibility.

5. When reviewing the data, consider the following issues, and record the assessment in the record of archived material:
   a. When was the data recorded onto the storage device
   b. How long does the device reasonably maintain data integrity under current conditions
   c. Is the hardware and/or software required to access data on the device expected to be readily available until the next review

6. If, as a result of this assessment, the current data storage device is considered inadequate, copy the data to a new device and update the record of archived materials to reflect the changes made.

7. If the current data storage device is considered adequate until the next review, document this on the record of archived data.

8. According to Health Canada Division 5 regulations, maintain all clinical trial records for a minimum of 25 years.

9. Take measures to ensure that the electronic data cannot be changed by making the files read only before storing, by storing on a read only device, or by restricting write access to the storage device to essential personnel.

10. It is not the responsibility of this site to archive electronic materials sent by another investigative site for the purposes of analysis only. In this case, it is the responsibility of the investigator at the site where the data was collected to ensure that the data is retained for the appropriate timeline. If original copies of the data are sent, arrangements should be made with the study sponsor or with the investigator-sponsor to return the materials once analysis is completed.

C. Retaining Case Report Forms

1. For sponsored studies, retention of case report forms is the responsibility of the study sponsor. Work with the study sponsor to archive the material and make a record of the process in the study files.

2. While Health Canada does not require the retention of CRFs, best practices dictate that these files be retained for 25 years from study closure or until analysis of study data is complete, whichever is longer.

3. Back up investigator CRFs on a regular basis using an automated system that allows for recovery of the data.

4. If data is lost or corrupted, take immediate steps to retrieve the data from the backup system. Assess the cause of the loss and take measures to prevent it happening again.

5. If a document contains identifiable information, the data must be stored securely. See SOP 506 – Information Access Control and Security for information regarding the safeguarding of identifiable information.