

Salford R&D Directorate	
Standard Operating Procedure: Retention of data, archiving and destroying documents	
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1.0 Background

All trial data must be kept so that the data can be accessed after the trial has finished. This may be necessary in the event of unexpected side effects after the trial drug has been approved. It is the responsibility of the sponsor and the Principal Investigator (PI) to ensure that these records are kept.

These data usually consist of trial documentation, such as Trial Master File and Case Record Forms and also the medical notes or hospital records of the participant. All must be retained and archived appropriately, so that they can be accessed after the trial is complete.

ICH Good Clinical Practice Guidelines (ICH GCP) are specific about which documents are essential for the conduct of a clinical trial, and which of these must be located in the Investigator's Study File (see R&D SOP : Study files and filing). The ICH GCP Guidelines (Section 5.5.11) state that essential documents be retained 'until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product'. Best practice for commercial organisations has traditionally been to retain documentation for at least 15 years.

Archiving is not expected to be the sole responsibility of the PI. ICH GCP Guidelines (Section 5.5.12) state the 'Sponsor should inform the Investigator(s)/Institution(s) in writing of the need for record retention and should notify the Investigator(s)/Institution(s) in writing when the trial related records are no longer needed'. It is the responsibility of the sponsor to inform the investigator(s)/Institution(s) when documents are no longer needed and can be destroyed.

Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

1.1 Purpose of SOP

To describe the procedure for archiving study documents at the end of a clinical trial and for retaining medical records for the required period.

1.2 Scope

2.0 Procedure

2.1 Who has responsibility for this SOP?

Clinical trial documentation can be archived by the PI or the sponsor. The PI must agree with the sponsor the exact requirements for local archiving and make or assist in making the necessary arrangements. The PI has a responsibility to allow the sponsor access to the archived data on request. The archived data can be audited by the sponsor or competent authority on request. The management of trial documentation and Study File may be the responsibility of a designated member of the research team, but the PI retains overall responsibility (see Trust Wide R&D SOP 008 - Delegation of Duties).

If the PI leaves the institution during the archival period, arrangements must be made to ensure the safekeeping and security of the archive information. Changes in personnel must be defined in the Study File and handover of responsibility documented.

2.2 When is the SOP required?

Archiving occurs as soon as possible after completion of a study. The planned end of a trial is normally considered as the date when the last patient has their last visit (at all sites, if it is a multi-site trial).

2.3 Procedure

When a PI receives confirmation that a study can be archived, reference should be made to the study contract or clinical trials agreement that should specify whether the PI or the sponsor is responsible for archiving the study. The sponsor must also be informed of the new arrangements. If the sponsor is the Trust, then the PI must inform the R&D Office of the location of the archived material which will be noted on the R&D management database. All documentation as defined in ICH GCP Guidelines (Sections 8.2, 8.3, 8.4) must be retained until notification from the sponsor. (These documents are clearly listed in Trust R&D SOP 016 -: Appendix A).

2.4 Trial documentation

All archived material should be stored in archive boxes that are clearly labelled with the name and reference number of the study, sponsor, PI and date to be archived until. See example in Appendix A. The archive boxes should be stored in a secure, dry location.

If the sponsor is an external organisation, then the PI must arrange for them to archive as soon as possible. Access to the material should be restricted to the PI and the regulatory authorities, however sponsors should be encouraged to fund storage of records as part of the contract.

Details of the archiving location should be recorded in a location register stored in the site office (example in Appendix B). The register should record the name and reference number of the study, sponsor, PI and date to be archived until. Whenever an item is retrieved from archive, the date, item and person retrieving the item should be documented, together with the date returned to archive.

2.5 Medical records

The patient's hospital notes must also be retained for at least 15 years after the completion of the trial. The inside cover of the notes must be annotated to indicate that the patient is part of a research study and the date until which the records must be retained by the Trust.

It should be noted that the Data Protection Office recommends that trial identifiers on patient notes are placed inside the patient's notes, and not on the cover, in order to protect patient confidentiality. After being labelled, the notes can be archived in the hospital/clinic filing system.

(The notes may be converted into electronic format by the Trust Medical Records department, and this record will be retained indefinitely by the Trust. All data should be made available if requested by relevant authorities.)

2.6 Destruction of documentation

Where the Trust is the sponsor, the reasons for destruction of essential documents should be documented and signed by the PI on behalf of the Trust. The record of destruction shall be retained for a further five years from the date that the essential documents were destroyed. The sponsor shall notify the investigators in writing when their trial records can be destroyed.

If any study data has been archived, details of the whereabouts of the data should be available for the inspector and written confirmation for the archiving site that the data will be maintained/stored according to Data Protection and GCP standards.

3. Other related procedures, policies, legislation or guidance

All other R&D SOPs, especially SOP 008- : Definitions of responsibilities and SOP- 016:
Setting up a study files and filing

International Conference on Harmonisation of Good Clinical Practice 1996

Data Protection Act 1998

4. Glossary

Good Clinical Practice (GCP)

Principal Investigator (PI)

5.0 Appendices

Appendix A: Example of Archive Label

Appendix B: Example of Archiving Log

Appendix A: Example of archive label

Sponsor Name, Protocol Number, Ethics Number _ _ _ / _ _

Protocol Title

Principal Investigator, Co-Investigator & Contact details

Department X, Hospital

Box [insert number] of [insert total number]
(Brief description of content)

Archive from [insert date] until [insert date]

Appendix B: Example of archiving log

Sponsor Name Protocol Number Ethics Number Protocol Title Investigator Directorate	____ / ____
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Please detail below the Case Record Form Numbers

Please indicate the number of archiving boxes, specific contents per box and exact storage location

	Contents of Box	Storage Location
Box 1		
Box 2		
Box 3		
Box 4		
Box 5		
Box 6		

- **Archive storage labels should be put on each storage box**
- **Any details regarding a change in storage during the archiving period should be documented**
- **The Investigator Declaration should be completed**
- **This log should be stored in a specified location by**

Principal Investigator Declaration <ul style="list-style-type: none"> • All essential documents are filed within the Investigator File as per the requirements of ICH-GCP • All consent forms are in the Investigator File in numerical order • The archive boxes will be stored as per requirements to conform to ICH-GCP
Principal Investigator signature
Date :.....