South Eastern Health and Social Care Trust

Standard Operating Procedures
(SOP)
Research and Development Office

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1.0	Sept 2007	Katrina Hughes	N/A
2.0	Aug 2011	Alison Murphy	Updated to new SOP layout. Expanded guidance and added explicit requirement to notify research office of archiving arrangements. Addition of appendices

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1. INTRODUCTION

Study documentation must be kept so that the data is accessible after the trial is completed. This is in case future studies may suggest a further period of follow-up, allegations are made of fraudulent behaviour, or if concerns arise about side effects and patients need to be contacted.

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 state that the sponsor and the Chief Investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial and that during that period are (a) readily available to the licensing authority on request; and (b) complete and legible.

The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines are specific about which documents are essential for the conduct of a clinical trial.

In current regulations, archiving is recognised as the responsibility of the Sponsor, which may be delegated to the Chief/Principal Investigator.

South Eastern Health and Social Care Trust is a research-active organisation, with a large number of active research at any time. Research at this level generates a large volume of paper records, which must be retained for some years at the end of a project. Therefore, a guideline for the storage of research data is necessary.

2. OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for archiving study documents in a clinical trial. Research-related data must be retained for a sufficient period after the end of a study to allow for audit and inspection by regulatory authorities, and should be available on request. This SOP describes the arrangements in place within SEHSCT for the storage of research data.

3. SCOPE

This SOP applies to all research within the South Eastern Trust where research essential documentation or research data is held by the Trust CI/PI.

4. PROCEDURE

4.1 Determining the end of the study

The end of study should be defined in the protocol, for example, when the last patient entered onto the study has had their last study visit.

4.2 When should documents be archived?

Essential documents need to be archived once the trial is completed e.g. the trial has undergone a final closeout visit, the closeout report issued and the final report written. The completion of a clinical trial shall be determined by the Chief Investigator and may vary among studies. The date of the completion of a clinical trial should be documented.

4.3 Who is responsible?

The Chief Investigator, on behalf of the SEHSCT as the Sponsor, is responsible for archiving of essential documents. In a multi centre study, the CI is also responsible for archiving of essential documents in the other sites which the Trust sponsors, although this can be delegated in writing to the Principal Investigators of each site. It is the responsibility of the Chief Investigator to inform the Principal Investigators at each site as to when these documents no longer need to be retained.

The Principal Investigator is responsible for archiving of essential documents at the respective sites in accordance with the requirements of the Sponsor (or CI if appropriate), the institution and local requirements.

The Investigator 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.

4.4 What documents should be archived?

All essential documentation as defined in ICH-GCP Guidelines (Sections 8.2, 8.3, 8.4) must be retained until notification from the Sponsor, i.e. Trial Master File, completed CRFs and source documents. Note: If source data is contained within medical notes, archiving should be in accordance with requirements of the host NHS Trusts.

Further information on the documents to be retained can be found in the SOP 13 ‘Essential Documentation and the Creation of Trial Master File’.

4.5 How should documents be archived?

Documents need to be stored in a way that preserves their integrity and readability and restricts access to appropriate individuals only. The media used to store essential documents shall be such that those documents remain complete and legible throughout the required period of retention and can be made available to the Sponsor, monitor, auditor, Ethics Committee, or regulatory authority upon request.

There are no regulations on the requirements for labelling archived essential documents. As guidance, all essential documents should be stored in archive boxes that are clearly labelled with the study title, reference number and trial site number (if applicable), the name of the Sponsor, CI and PI (if applicable), the date they were archived, and date to be destroyed (if available).

The archive boxes should be stored in a secure, environmentally controlled location, i.e. fire protection without water sprinkler systems, and water protection for humid conditions. Archive material should be stored in a legible condition.

A log should be kept by the CI/PI. of all documentation that is being stored. A template Archiving Record Form is contained in appendix 1

Details of the archiving location should be recorded by the CI and notified to the Sponsor. The Trust Research Office should be informed of the archiving arrangements and person responsible for archiving.

4.6 Access to archived records

Access to the material should be restricted to the named individuals responsible for the archives.

Upon request of the Sponsor, monitor, auditor, Ethics Committee, or regulatory authority, the investigator should make available for direct access all requested trial-related records.

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.

4.7 Transfer of ownership

If the CI/PI leaves the organisation during the archival period, arrangements must be made to ensure the safekeeping and security of the archive information. Any transfer of ownership of the data or of the documents shall be documented.

The Sponsor must be informed of the new arrangements.

The Trust Research Office should also be notified of any transfer of ownership.

4.8 How long should documents be archived for?

ICH GCP states 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”. Essential documents are defined as “those documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator sponsor and monitor with the standards of Good Clinical Practice and with all the applicable regulatory requirements”.

In the UK, The Medicines for Human Use (Clinical Trials) Regulations (2004, amended 2006) states that “The Sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial and that during that period are readily available to the licensing authority on request; and complete and legible.

The SEHSCT retention schedule states that primary research data should be retained for a minimum period of 5 years following completion of the study. This refers to all forms of research and not just clinical trials. Medical notes of participants in clinical trials must be retained for 15 years.

4.9 South Eastern Health and Social Care Trust Archiving Facilities

The Trust has access to off-site archiving facilities through third party contracts arranged through Business Services Organisation.

If records are being sent to off site storage facilities the Trust Records Management procedures should be followed.

PI is responsible for the cost of archiving. Any staff member embarking on a new research project within the Trust where storage of research data is to be required must allow for this when costing the project.

4.10 Destruction of Records

Once the required retention period has been reached records can be securely destroyed. A log must be kept of all documents destroyed, which should also include the following information,

Trial Identification (title and R&D reference number)
Date of destruction
Method of destruction
Signature of responsible person (usually CI/PI)

This log should be kept by the CI/PI

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS etc.

ICH GCP (1996), Section 5.5.11
Statutory Instruction 1928 (2006), 31A: Trial Master File and Archiving
SEHSCT Records Management Policy
SEHSCT Records Retention & Disposal Schedule
SEHSCT Records Management Document

6. APPENDICES

6.1 Appendix 1: Archiving Record Form
6.2 Appendix 2: Sample Archive Box Label

Appendix 1

ARCHIVING RECORD FORM

Please complete this form and make 2 copies
Copy 1: Place inside the box that you are archiving.
Copy 2: To be retained by CI/PI
Copy 3: To be submitted to Trust Research Office

Contact Details of Person Responsible for Archiving Clinical Research Data

Name		Designation	
Department		Telephone	
E-mail			

Name(s) of Persons Authorised to Access Archived Data

1.	2.

Details of Clinical Research Data Archived

Name of PI/CI		Department (if different from above)	
Study Title			
CTA No		Research Office Ref No	
Specify other study identifier if none of the above are applicable			
Period data refer to (mm/yyyy)		From to	

Archive Location

DATE AFTER WHICH DATA CAN BE DESTROYED	

Declaration
I confirm that the clinical research data, as detailed above has been archived

Signed: _____ Date: _____

Appendix 2

Sample Archive Box Label

Type of Records: Clinical Research Data

Title:

Ref No.:

Trial Site No. (if applicable):

Sponsor:

Chief Investigator:

Principal Investigator:

Date Archived:

Destruction Date:

Contact Name:

Contact No: