STANDARD OPERATING PROCEDURE FOR RESEARCH

Archiving and Destroying Documents

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SOP SUMMARY

To describe the procedure for archiving study documents at the end of a clinical trial.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

STANDARD OPERATING PROCEDURE: Archiving and Destroying Documents

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1. 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 to keep these records.

The ICH GCP Guidelines 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 CLPG19 SOP 18 - Study Files and Filing for Externally Sponsored Clinical Trials). The ICH GCP Guidelines (Section 5.5.11) state that essential documents must 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'.

Archiving is not expected to be the sole responsibility of the Investigator. 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.

2. PURPOSE

To describe the procedure for archiving study documents at the end of a clinical trial.

3. PROCEDURE

Clinical trial documentation can be archived by the Principal Investigator/designee or the Sponsor. The Principal Investigator must agree with the Sponsor the exact requirements for local archiving and make or assist in making the necessary arrangements. 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. The management of trial documentation and the Study File may be the responsibility of a designated member of the research team. The Principal Investigator at the site, however, retains overall responsibility (see SOPs for Definition of Responsibilities for Externally Sponsored Studies). If the Principal Investigator 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. The Sponsor must also be informed of the new arrangements.

WHEN?

Archiving occurs as soon as possible after completion of a study.

When an Investigator 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 Investigator or the Sponsor is responsible for archiving the study.

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 Appendix A of SOP Study Files and Filing for Externally Sponsored Clinical Trials.

All archived material should be stored in archive boxes that are clearly labelled with the name and reference number of the study, Sponsor, Investigator and date to be archived until. The archive boxes should be stored in a secure, dry location. If it is the Sponsor's responsibility, arrange for them to archive study contents as soon as possible. Access to the material should be restricted to the Investigator and the regulatory authorities.

Details of the archiving location should be recorded in a register stored in the site office. This register should record the name and reference number of the study, Sponsor, Investigator 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.

The patient's hospital notes must clearly identify that the patient has taken part in a clinical trial and that the notes should not be destroyed for a time limit of 15 years after death or discharge. After being so labelled, they can be archived in the hospital/clinic filing system. This procedure should be carried out in accordance with local hospital policies. All data should be made available if requested by relevant authorities.

4. DESTRUCTION OF ARCHIVED DOCUMENTS

DO NOT DESTROY any archived documents without the approval of the R&D

Manager. Trust Archivist – R&D Manager ([redacted]

5. OTHER RELATED PROCEDURES

CLPG19 SOP 6 - Definition of Responsibilities for Externally Sponsored Studies
CLPG19 SOP 18 - Study Files and Filing for Externally Sponsored Clinical Trials

6. REFERENCES

ICH-GCP, Good Clinical Practice Guidelines,
http://ichgcp.net/