

Standard Operating Procedure CCTU/SOP006

The CCTU Archiving Process

1. Scope

This Standard Operating Procedure applies to staff working on Cambridge-Sponsored CTIMPs or trials managed by the CCTU.

Research sponsored by external organisations that do not have alternative archiving arrangement in place can use this SOP for guidance.

For electronic systems please seek advice from the CCTU Archivist.

2. Purpose

The purpose of this SOP is to ensure that archiving is carried out according to:
The Data Protection Act 2018

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
Directive 2005/28/EC regulation SI 2006/1928

CUH Policy Records: Preservation, Retention and Destruction

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Essential Documents	Essential documents is the collective term for those documents that individually or collectively permit the evaluation of the conduct of a trial and the quality of the data produced. Essential Documents include the Trial Master File (TMF), source documents, Case Report Forms, Investigator Site File (ISF), Sponsor File and the Pharmacy File (if applicable). A minimal list of documents for archiving can be found in ICH GCP E6 (R2) Section 8 this list is not exhaustive and is for guidance only
TMF	The Trial Master File is a standard filing system which allows the effective storage and location of Essential Documents. The filing system can be in the form of a single project file or a number of files as deemed most appropriate. The TMF may also encompass Pharmacy, Laboratory, Data management Randomisation & Statistics files that may be held separately.
ISF	The Investigator Site File is a standard filing system which allows

	the effective storage and location of Essential Documents relating to the conduct of the study at the Participating Site. As with the TMF, the filing system can be in the form of a single project file or a number of files as deemed appropriate. The ISF may also encompass the Participating Site Pharmacy Files (if applicable)
CRF	Case Report Forms are printed, to record all of the information required by the protocol for each trial participant
Sponsor File	The Sponsor File comprises of a selection of Essential Documents which confirms compliance with sponsor's governance procedures and provides evidence of sponsor oversight and management of the trial. The Sponsor file also encompasses the sponsor pharmacy file (if applicable)
Pharmacy File	The Pharmacy File is a standard filing system which allows the effective storage and location of Essential Documents relating specifically to IMP Management and Dispensing Procedures (if applicable).
Trial Team	Any member of the research team can be but not limited to: PI, CI, Coordinator, research nurses, admin staff, lab staff, data staff
Archivist	Person appointed by the Sponsor to be the point of contact for the archiving process

3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
PI	Principal Investigator
CTO	Clinical Trial Officer
CRF	Case Report Forms
REC	Research Ethics Committee

4. Undertaken by

Staff trained to this SOP

5. Items Required

The relevant Checklist:

CCTU/TPL032 TMF Index

CCTU/TPL038 Local Pharmacy Site File Index

CCTU/TPL033 Investigator Site File Index

CCTU/TPL034 Site Information Index in the TMF

CCTU/TPL057 Sponsor File Index

- CCTU/FRM015 Archiving Box Label
- CCTU/FRM017 Archive Location Details
- CCTU/FRM109 Archive Box Tracking Log

6. Summary of Significant Changes

The trial file indexes are adapted for use as archiving checklists

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. Requirements

- Directive 2005/28/EC regulation SI 2006/1928
- Data Protection Act 2018
- The CUH Data Protection Policy and Procedure
- The CUH Records: Preservation, Retention and Destruction
- The CCTU acting on behalf of the sponsor must have a named Archivist

7.2. Responsibilities

7.2.1. The Sponsor:

- Is responsible for ensuring that all records and documents regarding the trial are archived
- Will determine when a trial is ready for archiving and the destruction date for the Sponsor File the TMF and ISF(s)
- Is responsible for archiving the Sponsor File and associated documents for Cambridge Sponsored CTIMPs this is delegated to the CCTU

7.2.2. Clinical Trial Officer/Governance Coordinator

- Clinical Trial Officers for are responsible for issuing the End of Trial Confirmation Letter issued by The Sponsor for CTIMPs
- R&D Governance Coordinators are responsible for confirming the end of trial date (one year from the date of the last correspondence to the REC/MHRA) for Non CTIMPs

7.2.3. Chief Investigator:

- Must ensure that the essential documents in the TMF and any participating site files (ISFs) are archived according to this SOP
- Must inform each site when these documents no longer need to be retained in archive, and to instruct that site to destroy those documents.

7.2.4. Principal Investigator:

- Must ensure that the Investigator Site File at their respective site(s) are archived according to this SOP and any local requirements stipulated in the Participating Site Agreement
- Ensure the location of the archive is documented use CCTU/FRM017
- Ensure systems are in place for retrieval and destruction of archive boxes

7.2.5. Named Archivist

- A named Archivist is a legal requirement for CTIMPs
- The QA manager is the Archivist for the CCTU, there can be named deputies; they are the point of contact for the archiving process carried out as specified in:
 - CCTU/SOP006 The CCTU Archiving Process
- The appointed Archivist takes responsibility for the management of archived boxes and the oversight of external archives, but takes no responsibility for completion of the archive checklist nor the physical preparation of archive boxes

7.3. When to Archive

Documents can be archived once all the files are reconciled and are complete.

7.3.1. CTIMPs

- The Sponsor issued end of trial confirmation letter signifies the end of all close out activities and regulatory reporting activities
- Documents can be archived from the date on the letter.
 - The retention period of the archived trial documents is stipulated in the letter
 - The retention period is calculated from the date on the EoT letter

7.3.2. Non CTIMPs

The trial documents can be archived one year from the date of the last correspondence to the REC/MHRA whichever the latest.

The responsibility for archiving the Sponsor file for Cambridge Sponsored non-CTIMPs resides with the Cambridge University Hospitals R&D department.

7.4. Where to archive

- Archive facilities can be sourced either onsite or offsite
- The CCTU takes no responsibility for the financial implications of an appropriate archive solution
- Contact the CCTU Archivist if you are unsure whether the facilities identified for storage are appropriate
- If the CCTU recommended off site provider is not used the sponsor should make a documented assessment of their suitability before use
- Archive facilities may be audited as directed by the Sponsor appointed Archivist to ensure the facility meets the following minimum requirements;
 - Restricted access
 - Elemental protection (including protection from fire & water damage)
 - Adequate space to host all boxes
 - Validation that boxes can be retrieved according to the agreement
 - Archive box tracking system
- The CCTU Archivist will maintain oversight of archive provider(s)

- If a label is not supplied by the archive provider use CCTU/FRM015 Archive Box Label

7.5. What to archive

- Where the CI is responsible for the TMF and is also the PI for the site the ISF and the TMF can be archived together
- Where files that are held in different locations e.g. pharmacy, statistics, randomisation, laboratory or data management they must be retrieved and merged with the appropriate file
 - Sponsor File,
 - Trial Master File
 - Investigator Site File

7.6. Documentation

When the trial is confirmed as closed Refer to 7.2.2:

- The relevant teams can start the archiving process
- The CCTU Archivist will create an archiving file in Q Pulse
- The teams will prepare and populate an archive checklist.
- For trials archived before the index has an archive section create a checklist by adapting the existing file index add a column for the bag number the box number and a tick box the indicate the documents are present
- Create a sign off at the end of the checklist

Populate:

- CCTU/FRM017 The Archiving Details Form
- CCTU/FRM015 Archiving Box label
- CCTU/TPL109 Archive Box Tracking Form

7.7. How to archive

Documents must to be stored in a way that preserves their integrity and readability. Trial documents must be legible and in their original format (wherever possible) for the full duration of the archiving retention period stated on the original application.

7.7.1. Best Practice

- Remove plastic wallets to prevent transfer of ink" sweating" onto the plastic
- Any documents which are prone to fading or wearing like waxed fax paper, ECG paper or overhead projector papers should be photocopied onto plain A4 paper for archiving purposes. If this is carried out, a member of the trial team should confirm the document as a certified copy (sign the new version, date and add a statement "true representative of the original version")
- Consider if any metallic administrative aids should be removed. Staples can remain in place where degradation is not likely to impair the text
- Contents of any one file should ideally be packaged together in large paper archiving envelopes or bags;

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- Plastic treasury tags (e.g. E-CLIPs can be used) should be used to replace the metal ring binders/lever arch files to bind the documents together as one set
- It is good practice to create an index for the top of each bound paper pack, and number each bag as shown in the diagram



7.7.2. Personal Identifiable Information (PID)

- Any documents that contain PID above that which have been approved in the regulatory submissions must be placed in separate sealed bags
- Seal securely and label with the document type e.g. (ECG printouts, recruitment logs) and marked as confidential
- Record as confidential on the checklist

7.7.3. Investigator Site Files

- The Participating Site ISF should not be sent to the Sponsor organisation
- For single centre trials where the TMF & ISF have been maintained as a combined file, they can be archived together
- The ISF can be archived once the site has been informed by the CI that the trial is closed
- All documents must be collected and incorporated into the site file including;
 - The local pharmacy file (where applicable)
 - Source documents (if source data is contained within the medical notes archiving should be carried out in accordance with the requirements of the host NHS Trust)
 - CRFs
- Participating sites including CUH are responsible for their own archiving in line with the Participating Site Agreement and their own Trust requirements
- Details of the Participating Site archiving arrangements should be recorded using CCTU/FRM017 Archiving Arrangements and a copy sent to the CCTU Archivist for the Q pulse archive record

- In cases whereby the participating site cannot be archived (e.g. inadequate facilities or insufficient funds), it is the responsibility of the CI to arrange for the ISF to be archived in collaboration with the lead site
- The ISF can only be requested by the delegated individuals at the participating site, not the CIs trial team or the Sponsor

7.8. Retention Period

- The retention period is calculated from the agreed end of trial date
- The retention period will be recorded on:
 - CCTU/FRM017 Archiving Details
 - CCTU/FRM015 Archive Box Label
 - Q pulse

Type	TMF and Site Files	Sponsor Files
Non-CTIMP	5 years	30 years
CTIMP	5 years (unless otherwise stipulated in the end of trial confirmation letter)	30 years
Advanced therapies	30 years	30 years
Paediatric	Until the youngest participant reaches the age of 22 or for 5 years after the end of the trial, whichever the longer	30 years

7.8.1. Consolidating the archive boxes

- Populate the box label CCTU/FRM015 print onto sticky backed paper and attach to the archiving box
- The location (e.g. bag and box number) should be recorded on the checklist
- File a copy of the completed checklist inside each box and send an electronic copy to the Archivist
- Do not overfill the boxes. The archive box lids should fit comfortably. Do not seal the archive boxes
- Complete form CCTU/FRM017 Archive Location Details and send to the CCTU Archivist
- Populate the Archive Tracking Log CCTU/FRM109 and give to the CCTU Archivist for completion
- The Archivist is informed that the documents have been prepared for archive and handed over

7.9. Handover to the Archivist

Transfer of custody will be made by completion of:

- CCTU/FRM017 Archiving Details
- CCTU/FRM109 Archive Tracking Log

Once the CCTU Archivist has confirmed receipt and completion of these documents, they will take responsibility for the management of the collective boxed documents.

7.10. Archive Costs

The CCTU has no responsibility for any unscheduled or unapproved payments of archiving costs.

It is the responsibility of the CI or PI as delegated to review archiving costs and ensure that funds are available.

Archiving costs can include:

- Off-site archiving service providers
- Archiving materials, e.g. boxes, treasury tags, archiving bags, suitable fire proof lockable cupboard
- Trial staff resource

7.11. Access to Archived Documents

Access to archives is restricted to the named Archivists.

7.12. Q Pulse Record Management

The named Archivist will record all the paperwork in Q Pulse

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

- The Institute of Clinical Research, Abbreviations used in Clinical Trials.
- MHRA, Good Clinical Practice "Grey Guide"
- EU Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001
- EU Directive on Principles and Guidelines for Good Clinical Practice Commission Directive 2005/28/EC
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

10. Associated Documents

Corporate Policy, Records: Preservation, Retention and Destruction

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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