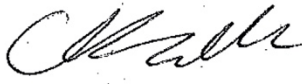




SOP Number 005

SOP Title Archiving of the Trial Master File and Essential Documents

| | Name | Title | Signature | Date |
|---|---------------|---|--|-------------|
| Author on behalf of the QA Focus Group | Clare Riddle | Senior QA and Compliance Manager, Clinical Trials and Research Governance |  | 24 OCT 2018 |
| Reviewer on behalf of the QA Focus Group | Elaine Chick | Deputy Head of Clinical Trials and Research Governance |  | 24 OCT 2018 |
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|--------------------------|-------------|
| Agreed by QA Focus Group | 18 OCT 2018 |
| Effective Date | 03 DEC 2018 |
| Review Date | 02 DEC 2021 |

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1. PURPOSE

The purpose of this SOP is to describe the standard procedures to be followed when archiving essential documents related to clinical trials conducted under the auspices of the University of Oxford.

2. INTRODUCTION

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 states that the Sponsor shall ensure that the documents contained, or which have been contained, in the Trial Master File/Investigator Site 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.

In line with the regulations, the University of Oxford requires that all essential documents be retained for at least 5 years after the completion of a clinical trial (as defined in the protocol) or for a longer period where so required.

3. SCOPE

The scope of this procedure is for all clinical research studies sponsored by the University of Oxford, but may also be used for other research studies at the discretion of the unit.

4. DEFINITIONS

Essential Documents

Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

Trial Master File (TMF)

The Trial Master File consists of essential documents, which enable both the conduct of a clinical trial and the quality of the data to be evaluated. ICH GCP defines that the TMF consists of a Sponsor File and an Investigator Site File.

NOTE: For University of Oxford sponsored studies, the Clinical Trials and Research Governance Team will hold documentation demonstrating Sponsorship oversight. This documentation is not considered part of the TMF and as such is outside the scope of this SOP.

- **Sponsor File (units may use other terms)**

The Sponsor File consists of essential documents relating to study conduct held by the Sponsor delegate.

- **Investigator Site File (ISF)**

The Investigator Site File consists of essential documents relating to study conduct at a specific site (i.e. location where participant-related study activities are actually conducted), and which enable both the conduct of a clinical trial and the quality of the data at that site to be evaluated. This may be incorporated into the TMF if the trial consists of one site only.

Source Documents

A source document is any document in which data collected for clinical research is first recorded, for example medical records, lab reports, diary cards, x-rays, ECG printouts and pharmacy dispensing records. If specified in the protocol, the Case Report Form (CRF) will be considered as the source document if it is the first point of data entry.

Personal data

Data which relate to a living individual who can be identified from those data, or from those data in combination with other accessible information. This includes names, addresses, NHS numbers, dates of birth, as well as combinations of data which together might identify an individual (e.g. a dataset containing hospital, gender, age, dates).

Case Report Forms (CRFs)

A printed, optical or electronic document designed to record all of the protocol required information on study participants.

5. RESPONSIBILITIES

Sponsor

The Sponsor has overall responsibility for archiving of essential documents. This may be delegated to the Chief Investigator in a written agreement.

Chief Investigator (CI)

The Chief Investigator, where delegated, is responsible for archiving. In a multi-centre study, this may be delegated to sites within a written agreement.

Named Archivist

Named individual, identified by the Sponsor or delegate, to be responsible for archiving arrangements for TMF documents, restricting access to approved individuals, and recording archiving details, including location, tracking and destruction date.

6. SPECIFIC PROCEDURE

6.1 What to Archive

The TMF including all essential documents must be archived including, for example, laboratory and pharmacy records. Note: If source data is contained within medical notes, archiving should be in accordance with requirements of the host healthcare provider. Consideration should be given to whether personal data which does not form part of the essential documents needs to be archived, redacted or destroyed.

Records that are not trial specific, for example SOPs, training records, equipment records, must also be retained.

Documents may be in paper or electronic format. The principles of archiving paper records should also be applied to electronic records to ensure their completeness, accessibility and security.

6.2 When to Archive

The TMF including essential documents need to be archived once all study-related activity is completed.

6.3 For How Long Should the Essential Documents be Archived?

The TMF including all essential documents must be retained for at least 5 years after the completion of study-related activities, or for a longer period where so required e.g. genetic studies or national laws. If the clinical research involves minors under 18 years old, essential documents

should be archived until 3 years after the youngest subject reaches 18 years old, or 5 years whichever is longer.

Non-trial specific documents must be retained for the same length of time of any relevant trial that they relate to, is archived.

6.4 How to Archive

Documents need to be stored in a way that preserves their accuracy, integrity and legibility, and restricts access to authorised individuals only. The medium of storage should take into account the ability to retrieve in light of developing technologies replacing obsolete systems. Any alteration of records should be traceable.

The Investigator must make available all requested study material upon request of the Sponsor, auditor, Ethics Committee or Competent Authority.

Files of essential documents should be labelled with the study title reference number and trial site number (if applicable), the name of the CI and PI (if applicable), the date they were archived, and date to be destroyed (if available).

The Named Archivist must maintain a record of details of archived documents. Records should include details of the clinical research, archiving location and person authorized to access these documents, the date they were archived, and date to be destroyed.

A document should be created to assign ownership to the Named Archivist to provide continuity in the event of the CI/PI being no longer available. If the CI leaves the University, agreement must be reached with the Sponsor as to continued ownership of the archived documents.

6.5 Where to Archive

The data both paper and electronic should be archived appropriately (consider space, security, fire protection without water sprinkler systems, water protection, humid conditions, pests etc.).

If appropriate, a professional external archive site may be utilised. There should be assurance that such facilities are fit for purpose, and a contract must be in place. In this event, there must be an adequate and recorded tracking process, including storage and secure transmission of documents.

6.6 Retrieval

Retrieval must be justified, authorised and document. Documents retrieved must be similarly returned to archive in the same state as soon as practicable.

6.7 Destruction

At the conclusion of archiving, documents may be destroyed with Sponsor or delegate authorisation and according to local procedures and regulations. A documented record of destruction should be retained by the Named Archivist.

7. RELATED DOCUMENTS

University of Oxford Core SOP 013 – Confidentiality and Data Security

8. REFERENCES

The Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments)
General Data Protection Regulation (GDPR) and Data Protection Act 2018

9. CHANGE HISTORY

| Version No. | Effective Date | Significant Changes | Previous Version No. |
|-------------|----------------|--|----------------------|
| 1.0 | 01 Jan 2014 | First version of SOP | n/a |
| 2.0 | 19 Jun 2017 | Redefined definitions to align with other Core SOPs. Added additional information about essential documents that are generic across multiple studies and electronic archiving. | 1.0 |
| 3.0 | See page 1 | Redefined definitions and updated reference to new data protection legislation. | 2.0 |