brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

Archiving Paper Trial Documents (for BSUH as a Sponsor)

SOP Reference:	**SOP/RD/033**
Version Number	**Final V.2.0**
Date:	**05th Jan 2017**
Effective Date:	30th Jan 2017
Review by:	30th Jan 2020

Author: Gemma Earl **Designation:** Deputy Head of R&D: Trial Management and Quality Assurance Brighton & Sussex University Hospitals NHS Trust	**Signature**	**Date** 05Jan17
Authorised By: Scott Harfield **Designation:** Head of Research and Development Brighton and Sussex University Hospitals NHS Trust		5/1/17

Version	Date	Reason for Change	Author
2.0	13th Aug 2009	Change in review and implementation policy	Linda Henderson
3.0	13th January 2014	SOP required review and update. Addition of BSUH sponsored, multi-centred archiving arrangements	Gemma Earl
4.0	17th February 2014	Alert sticker process to flag research participants to Health Records has changed	Gemma Earl
1.0	5th February 2016	Separation of sponsor and site archiving into 2 SOPs	Hannah Butler
2.0	08th Nov 2016	Training, Cross Referenced SOPs and References sections added	Gemma Earl

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for archiving study documents in a research study being sponsored by Brighton and Sussex University Hospital (BSUH).

2.0 Introduction

Essential documents must be kept so that trial data remains accessible after the study has been completed. The documentation may be needed for a number of reasons including:

- Future studies suggesting a further period of follow-up
- Allegations of fraud
- Patients needing to be contacted due to concerns over side-effects
- Compliance with audit or inspection requirements

Commission Directive 2005/28/EC dated 8th April 2005, Chapter 4, Article 19 states that:

"The sponsor shall appoint individuals within its organisation who are responsible for its archives. Access to archives shall be restricted to the named individuals for the archives".

Please refer to the site archiving SOP (SOPRD004 Archiving Paper Trial Documents – For BSUH as a Research Site) for the details of the off-site archiving facilities contract. The R&D department should be contacted for any archiving queries or requests. Essential documents should be archived once the trial has been completed, the end of trial declaration has been submitted and the clinical study report completed (see SOP/RD/009 Notification of End of a Trial).

3.0 Responsibilities

Named Archivist

The named archivist for the Research & Development department (R & D) is responsible for the coordination and compliance of all archiving performed. This includes the following functions:

- Sending documents for archiving
- Retrieving documents from archiving
- Authorising destruction of archived documents

Chief Investigator (CI)

It is the responsibility of the CI to ensure that all the essential documents are correct and complete before sending them to the archivist for transfer off-site. This responsibility may be delegated to another member of the research team but must be recorded on the delegation log.

Sponsor

It is the sponsor's responsibility to ensure the essential documents are archived. For multi-centred studies, Investigator Site File archiving is delegated to the Principal Investigator at each site.

It is the sponsor's responsibility to inform the Principal Investigator (PI) at each site when documents can be destroyed or are ready for archiving at the end of the study.

4.0 Procedure

The essential documents for the sponsor are maintained within the Trial Master File (TMF). The ISF from sites should not be sent to the sponsor for archiving unless the sponsor and investigator are essentially the same organisation (i.e. for smaller BSUH sponsored studies, with BSUH as the only site). This is further described in the Essential Documents SOP.

Specific information on preparing and sending documents for archiving, also for retrieving, returning and destroying archived documents are described in the Archiving Paper Trial Documents (For BSUH as a Research Site) SOP.

The sponsor is responsible for ensuring that there is an appropriate archiving procedure for essential documents held at each site.

The SOP on Essential Trial Documentation (SOPRD007 Essential Document Management)provides guidance on the definition of an essential document.

A full review of the TMF should be carried out and documented prior to approval to archive being given. Unless the study documentation stipulates that the ISF needs to be retained at site until the final published report is available, the ISF can be archived prior to this.

For multi-centred studies where BSUH is the sponsor, the clinical trial agreement with each site will document that it is each participating research site's responsibility to maintain and archive study documentation for their site. The TMF will contain details of the participating sites local archiving arrangements. This will include location of archive and Named Archivist contact details.

For CTIMPs and other research studies, a close out monitoring visit may be performed by the CTM prior to archiving and a close out monitoring report produced. BSUH will inform PIs at participating sites when the essential documentation is ready to archive.

TMFs and ISFs for BSUH sponsored trials should normally be archived for at least 5 years unless otherwise specified by the funder of the research trial or if the data is to be used for a Marketing Authorisation. In studies where the data is used to support a marketing authorisation, documents should be retained for at least 15 years after completion of the study. Trial participants' medical records must be retained for at least 5 years.

BSUH will inform the PIs of sites when the archived documents can be destroyed.

5.0 Training

This is a 'read and understand' SOP. Evidence of having read and understood this SOP should be provided on your SOP Training Matrix.

Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross Referenced SOPs

SOPRD004 Archiving Paper Trial Documents – For BSUH as a Research Site

7.0 References

ICH GCP (1996) Section 5.5

Statutory Instrument 1928 (2006), 31A: Trial Master File & Archiving

MHRA Grey guide Good Clinical Practice 2012