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Brighton and Sussex University Hospitals NHS Trust

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Essential Documentation Management

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Version	Date	Reason for Change	Author
1.0	13th Jul 2010	Review required. Updated with QA team involvement. Retention and Archiving sections added	Gemma Earl
2.0	21st Mar 2014	Minor updates to content	Gemma Earl
3.0	12th April 2016	Updated to the R&D Trial Management team. Archiving SOP has been split into 2 – sponsor and site specific	Hannah Butler
4.0	04th Nov 16	Removal of references to CTIMPs & SOP Training Matrix	Gemma Earl

1.0 Purpose

This SOP describes the management of essential documentation for Brighton and Sussex University Hospital NHS Trust (BSUH) sponsored research. The purpose is to provide a standard format for all BSUH sponsored research studies in the preparation and maintenance of essential documents. This SOP is only applicable to studies that are **not** managed by the Brighton & Sussex Clinical Trials Unit.

2.0 Introduction

Essential documents are documents relating to a research study that enable the conduct of the trial and quality of the data generated to be evaluated and to demonstrate whether the trial has been conducted in accordance with the applicable regulatory requirements, guidance and standard operating procedures.

A Trial Master File (TMF) is a repository of all information relating to a research study that is necessary to reconstruct it. It should contain all essential documents, providing a robust record of all aspects of the research study. The International Conference on Harmonisation Good Clinical Practice guidelines (ICH GCP) requires that TMFs should be established at the beginning of a trial and maintained throughout.

If the study is multi-centred, then an Investigator Site File (ISF) is required at each participating site, in addition to the TMF. The ISF should contain all the essential documents at the individual investigator site where the research is being conducted.

Where BSUH is the sponsor and the study is single centred, the ISF and TMF may be combined

3.0 Responsibilities

Chief Investigator (CI)
The CI is responsible for the production, maintenance & archiving of the TMF. This activity may be delegated to other members of the team.

Principal Investigator (PI)
The PI is responsible for the maintenance & archiving of the ISF although this duty may be delegated to other members of the research team and must be documented on the delegation log.

All Members of the Research Team
All members of the research team are responsible for ensuring the security of the essential documents throughout the trial.

4.0 Procedure

Essential documents are very important particularly if the study will be key in determining treatment via its publication or influencing national guidelines.

4.1 Content of TMF/ISF

The TMF containing the essential documents should be established as soon as possible after BSUH have agreed to sponsor the study.

The TMF will be set up using the Index for Trial Master File (RD/T009). If the study is multi-centred, each participating research site will need an ISF. The ISF will be set up using the Index for Investigator Site File (RD/T008). These indexes should be interpreted by researchers and best practice applied in the context to the type of research they are conducting. If sections of the index do not apply to the research study, this should be noted as n/a on the index of the file.

A file note must be made and kept within the appropriate section of the TMF/ISF for any essential documents that are kept elsewhere. The file note must detail the precise location of the essential document and be signed and dated by the appropriate member of the research team.

The TMF should be labelled on the spine with a minimum of study title, REC reference, IRAS number and CI name. The ISF should be labelled in the same way with the addition of the PI at that site. The TMF and ISF may have several volumes. If this is the case then each volume should be labelled with volume number x of y on the spine label.

Separate folders can be set up to hold TMF or ISF documents during the study. E.g. Data Management, Statistics or laboratory information. However, these must be collated with the TMF/ISF at the close of the study as they are essential documents.

Access to the essential documents must be granted to authorised monitors, auditors and regulatory authorities. The documentation should be kept up to date and filed in the TMF/ISF in a timely manner.

4.2 Version Control

All essential documents must be version controlled. The documents should have a unique document identifier so that different versions can be distinguished. This identifier should be on every page of the document along with page numbers (x of y recommended). Superseded versions of all essential documents should be retained in the file and marked clearly as superseded so that they are not inadvertently used.

4.3 Retention

The essential documents should be retained for at least 5 years after the conclusion of the study, unless the study is a CTIMP, then the essential documents should be kept for 25 years from the end of the trial. It is the responsibility of the sponsor to inform research sites when the documents no longer need to be retained and can be destroyed.

Research participant health records should be retained for at least 5 years after the end of the research study and in accordance with the maximum period of time permitted locally at the research site.

At BSUH, research participant's health records must be flagged using a pink sticker on the outside front cover of the participant's health record to avoid premature destruction. An R&D sticker must also be placed inside the front cover of the health record indicating when they can be destroyed. This flags to the health record department that the participant is taking part in a research study and the records shouldn't be disposed of until the date of destruction on the inside cover (please refer to SOPRD004 Archiving of Paper Documents for BSUH as a Research Site).

4.4 Archiving

Following the closure of a study the essential documents should be archived in accordance with the SOPs on Archiving Paper Documents for BSUH as a Research Site (SOP/RD/004) and Sponsor (SOP/RD/033).

5.0 Training

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete 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 Reference SOPs

SOPRD004 Archiving of Paper Documents for BSUH as a Research Site
SOPRD033 Archiving of Paper Documents for BSUH as a Sponsor

7.0 References

MHRA, Good Clinical Practice Guide, Chapter 10, pg 329-351, TSO information & publishing solutions, 2012