York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S44

The Pharmacy Clinical Trial File

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Author:	Abigail Rowbotham
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Approved by:	Name/Position:	Poppy Cottrell-Howe – Pharmacy Clinical Trials Manager
	Signature:	Signed copy held by R&D Unit
	Date:	18th March 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	18th March 2019

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	8th November 2010	
2.0	4th March 2013	Removal of references to the North and East Yorkshire R&D Alliance. Change of SOP Controller. Removal of reference to conditional permission, addition of Scarborough hospital as a site working to this SOP. Changes to referenced SOPs included in this SOP. Change to PharmF52 – Pharmacy Clinical Trial File Contents.
3.0	29th May 2015	
4.0	15th April 2019	Change of author and change of link to R&D website. Changes to reflect updates on other SOPs and referenced to related documentation. Added sections on colour coding of files and file labels.

Contents

1 Introduction, Background and Purpose

In an NHS Trust that sponsors or hosts clinical trials of Investigational Medicinal Products (CTIMPs), the Trust's Pharmacy department has a key role. To enable it to fulfil that role and exercise appropriate control over all aspects of Investigational Medicinal Product (IMP) handling, a properly maintained file containing the required documents for each sponsored or hosted CTIMP must be kept in Pharmacy. The purpose of this SOP is to set out the requirements for compiling and maintaining the Pharmacy Clinical Trial File for each CTIMP.

2 Who Should Use This SOP

This procedure applies to all staff working within the Pharmacy Clinical Trials as part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used when printing, filing, updating, and superseding of documents and resources within the pharmacy clinical trial file (pharmacy site file – PSF). This should be done throughout all the stages of keeping documentation/PSF, including assessing the studies feasibility, preparing the study for opening, during maintenance of the Pharmacy Clinical Trial File and when the trial is closed out with the Trial Master File (TMF) / Investigator Site File (ISF) is prepared for archiving.

This SOP applies to all Pharmacy Clinical Trial Files, whether for sponsored or hosted trials – including those for which the Investigator Site File has been set up by an external Sponsor in accordance with their own SOPs.

4 Procedure(s)

The Pharmacy Clinical Trial File or Pharmacy Site File (PSF) for each CTIMP will contain two categories of document:

- Original documents that form part of the TMF / ISF
- Copy documents that may not form part of the TMF / ISF but are needed in Pharmacy for ease of reference.

4.1 Preliminary Documents

Pharmacy will receive a copy of the protocol or minimal information of a study when it is first proposed. Feasibility will be assessed (stage 1) and the relevant section of the Pharm/F14 – Pharmacy Clinical Trial Set up Form should be completed. This form must be printed along with the information received about the study and placed in a card wallet file labelled with the name of the proposed study and the date it was received. Wallets when labelled are kept in a filing cabinet labelled (expressions of interest – EOIs)

4.2 Preparation of the Pharmacy Clinical Trial File

A research facilitator will request that the Pharmacy Clinical Trials Team begin the set-up of the Pharmacy Clinical Trial File/Pharmacy site file for a particular trial. The papers from the card wallet should be transferred into the lever arch file.

Red files should be used for studies based on the Scarborough site, black or white files should be used for all studies based on the York site.

A laminated label should be fixed to the spine and the front of the lever arch file containing the following items of information:

- Short title of trial
- R&D reference
- EudraCT Number
- Chief / Principal Investigator name
- Sponsor of the study
- Pharmacy supplies location for the trial
- IMP used in the study
- The number of file e.g. file number 1

Studies ran at the Scarborough site are marked with SGH on the label also.

During the point of printing and laminating the file signs, create small signs with the trial name to use on the end of the roller shelves to show which shelf the file is kept on.

The colour of the label for the file will be representative of the speciality it is. Copies of the key for the colour coding of file labels is kept within the pharmacy clinical trials office and dispensary.

The Pharmacy Clinical Trial File should be stored in a secure designated area at all times.

4.3 Contents of the Pharmacy Clinical Trial File

The lever arch file should be equipped with numbered dividers for the sections that are listed in Pharm/F52.

A copy of Pharm/F52 should be placed at the front of the file to act as a contents guide.

As indicated in Pharm/F52, some sections should contain original documents and some should contain copy documents. For example, the original Protocol signed by the CI / PI will be retained in the Investigator Site File and Pharmacy will have a copy. Similarly, all original contracts will be retained by the R&D Unit; Pharmacy will have copies of all contracts that are relevant to it.

The dispensing instructions and procedures for handling the IMP for the clinical trial are an important part of the Pharmacy Clinical Trial File. The process of producing these instructions and study specific procedures are described in Pharm/S50 (Preparation, Review and Approval of Pharmacy Study Specific Trial Instructions). Once these procedures are written and approved the

original wet signed copy will be printed on yellow paper and laminated, before placing within the relevant section of the Pharmacy Clinical Trial File.

4.4 Maintenance of the Pharmacy Clinical Trial File

All members of the Pharmacy Clinical Trials Team are responsible for ensuring that Pharmacy Clinical Trial Files are maintained. This is outlined within Pharm/S39 - Maintaining Pharmacy Clinical Trial Files.

The Pharmacy Clinical Trial File contains a significant component of the TMF / ISF. There must be a complete audit trail of all activity undertaken for the trial – sufficient to allow the trial to be recreated from the paperwork; and the paperwork should be ready for monitoring or inspection at any time. It follows that:

- File maintenance must be meticulous.
- Any events or decisions not otherwise provided for should be recorded in dated and signed file notes.
- Any corrections that need to be made to the documentation should be made so that the original entry is not obliterated – a correction entry should be made, with the date of the change and signature of the person making it.
- Particular care should be taken to ensure that amendment notifications are properly filed on receipt, so that all staff is working to the correct, up to date, version of the protocol or other documents.

4.5 Closure/archiving of the Pharmacy Clinical Trial File

When requested by the sponsor or research team**,** the Pharmacy Clinical Trial File can be prepared for archiving. This is done by following Pharm/S56 Trial Closedown in Pharmacy.

5 Related SOPs and Documents

Pharm/S56	Trial Closedown in Pharmacy.
Pharm/F14	Pharmacy Clinical Trial Set up Form
Pharm/F52	Contents of Pharmacy File
Pharm/S39	Maintaining Pharmacy Clinical Trial Files