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 R&D Newsletter 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html

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	Date:	27th April 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	27th April 2015

This SOP will normally be reviewed every 2 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	

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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 Team at York and Scarborough Hospital as part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used

- when keeping documents on a proposed trial for purposes of considering its implications for Pharmacy.
- when preparing the Pharmacy Clinical Trial File for a CTIMP following issue by the R&D Unit of NHS Permission to conduct the trial in the Trust, in accordance with R&D/S14, and prior to Confirmation of Pharmacy Readiness in accordance with Pharm/S41.
- when maintaining the Pharmacy Clinical Trial File during the conduct of the trial, to ensure the most up to date documents are used.
- when the trial is closed out and 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 following paragraph is copied from R&D/S09 (Set-Up and Management of Research Studies):

It is often convenient for some of the contents of the TMF/ISF to be kept by Trust departments such as Pharmacy or Laboratories. The essential requirement is that all the documents a particular Site should have are within that Site. They need not all be in the same lever-arch file or in the same location within the Site, but it must be possible to assemble the whole TMF/ISF immediately if required for monitoring or inspection. All files should contain numbered sections with file dividers as set out in the Contents of TMF/ISF

Form; where some sections are empty because the corresponding section is used in a file held by another department at the Site, a cross-referencing file note must be inserted using the appropriate template.

The Pharmacy Clinical Trial File for each CTIMP will contain two categories of document:

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

When the trial is closed out, documents in the first category will be put together with documents held elsewhere in the Trust to form the whole TMF / ISF and will be archived accordingly. Documents from the Pharmacy Clinical Trial File will be stored in Section 16 of the ISF or section 17 of the TMF, with the copy of Pharm/F52 that had been used in Pharmacy Clinical Trial File. Documents in the second category will be copies of originals held elsewhere. When the trial is closed out and the TMF / ISF prepared for archiving, the copies will be destroyed.

4.1 Preliminary Documents

Pharmacy will receive a copy of the protocol when it is first proposed that the trial should be sponsored or hosted in the Trust. By the time the trial receives NHS Permission there will be a number of other documents in Pharmacy. During this period all documents for a particular trial should be kept in a filing cabinet within a secure area in Pharmacy, in a card wallet file labelled with the name of the proposed local Chief / Principal Investigator, the short trial title and the R&D Reference (as soon as one is allocated to the trial). Refer to Pharm/S40 (Receipt of the Clinical Trial Protocol and Associated Agreements).

4.2 Preparation of the Pharmacy Clinical Trial File

When NHS Permission for the trial is issued by the R&D Unit the letter will be copied to Pharmacy. As soon as this copy letter is received a member of the Pharmacy Clinical Trials Team should set up the Pharmacy Clinical Trial File for the trial in a lever arch file. The papers from the card wallet should be transferred into the lever arch file.

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

- Short title of trial
- R&D reference
- EudraCT Number
- Chief / Principal Investigator name
- Pharmacy supplies location for the trial

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

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 completed on template Pharm/T25, these procedures will constitute the standard operating procedure to be followed by the Pharmacy Clinical Trial team when dispensing or handling the IMP for that trial.

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 in accordance with R&D/S09 (Set-Up and Management of Research Studies) and R&D/S07 (Implementing Amendments for Research Studies NOT Sponsored by the Trust).

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, in accordance with R&D/S07, so that all staff are working to the correct, up to date, version of the protocol or other documents.

5 Related SOPs and Documents

R&D/S07	Implementing Amendments for Research Studies NOT Sponsored by the Trust
R&D/S09	Set-Up and Management of Research Studies
R&D/S14	Granting NHS Permission
Pharm/S40	Receipt of the Clinical Trial Protocol and Associated Agreements
Pharm/S41	Pharmacy Trial Assessment and Confirmation of Readiness
Pharm/S50	Preparation, Review and Approval of Pharmacy Study Specific Trial Instructions
R&D/F11	Investigator Site File Contents (Hosted Studies)
R&D/F95	Trial Master File Contents List
Pharm/F52	Pharmacy Clinical Trial File Contents
Pharm/T25	Pharmacy Trial Instructions