

Maintaining Pharmacy Clinical Trial Files

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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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	18 th July 2016	New SOP

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1 Introduction, Background and Purpose

It is important to ensure that all Pharmacy Clinical Trial Files are kept up to date and complete.

This Sop describes the process of maintaining Pharmacy Clinical Trial Files.

2 Who Should Use This SOP

This SOP should be followed by all members of the Pharmacy Clinical Trials team at York and Scarborough Hospitals, which form part of York Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used on a regular basis when maintaining Pharmacy Clinical Trials Files.

4 Procedure(s)

Procedure for maintaining Pharmacy Clinical Trials Files.

During this procedure, a member of the Pharmacy Clinical Trials Team is required to carry out a Pharmacy Clinical Trials file maintenance check following the Pharmacy Clinical Trials File Maintenance form (Pharm/F82)

All Pharmacy Clinical Trials Files will need to be maintained on a regular basis. The frequency at which file checks are carried out will be determined by the number of patients recruited to individual trials and other contributing factors.

Individual trial monitors should be contacted in order to obtain a list of current working documents so that we can ensure that we are working to the correct versions of all documents.

1. Obtain a blank copy of the Pharmacy Clinical Trials File Maintenance form (Pharm/F82)
2. Locate the Pharmacy Clinical Trial File for the individual trial which you are wishing to carry out the check.
3. Contact the trial monitor in order to obtain a list of current working documents for the trial (contact details should be located on the trial information sheet inside the front of the file).
4. Work through the file filling in the Pharmacy Clinical Trials File Maintenance form with any documents that are missing or incomplete, working against the list of current working documents sent by the monitor.
5. If any of the documents currently in use in the file are not the current versions that should be being used replace these with the current version, supersede the old version and place these in the superseded section of the Pharmacy Clinical Trial File.

6. If any of the documents being used in the Pharmacy Clinical Trial File have been produced by the trust, ensure that these are in date and the current approved version is in use. If any of these documents require replacing put the new version into the file and supersede the old version of the document and place the superseded version into the superseded section of the Pharmacy Clinical Trial File.
7. If any patient prescriptions or accountability information is missing and cannot be located, write a file note for each of these instances and record these on the file note log.
8. Print any correspondence relating to the trial and file this in the correspondence section of the Pharmacy Clinical Trial File.
9. On completing the Pharmacy Clinical Trial File maintenance check, file the Pharmacy Clinical Trials File Maintenance form (Pharm/F82) in the Pharmacy Clinical Trials Maintenance Form folder in the clinical trials dispensary.

5 Related SOPs and Documents

Pharm/F82 Pharmacy Clinical Trials Maintenance Form