York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S56

Trial Closedown in Pharmacy

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Date:	8th February 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	1st February 2011	
2.0	22nd July 2013	Removal of references to the North and East Yorkshire R&D Alliance. Change of SOP Controller.
3.0	20th August 2015	Minor amendments
4.0	8th March 2019	Change of author and changes to reflect new Pharmacy Trial Closedown Form. Change of link to R&D website

Contents

1 Introduction, Background and Purpose

During the closedown of a trial, it is an important requirement to ensure that all the documents that provide an audit trail are present in the Pharmacy site file. The Pharmacy site file and documents contained within are required to complete the trial master site file and therefore at all times should contain the essential documents relating to the clinical trial.

This SOP describes a procedure for or preparing a pharmacy related study for archiving or closing down.

This SOP should be used in conjunction with the relevant R&D – Trial Close out SOP's.

A trial site can be considered closed when all study related activities at a particular site are reconciled and/or completed.

The exact date of closure of a clinical trial will be defined by the Sponsor, and the Pharmacy department will be notified by the Sponsor in advance of the closure of the trial in writing. However a sponsor or research team may ask for a study to be prepared for archiving prior to the close out date has been arranged. For commercial trials, this communication may come from the Clinical Research Associate, or for non-commercial trials, the Trial Manager of the relevant study. For trials Sponsored by York Teaching Hospital NHS Foundation Trust, this notification will come from the R&D Unit.

The closure of a clinical trial within Pharmacy will usually take the form of a trial close-out visit conducted by the trial Sponsor. However, in some circumstances, the trial Sponsor will request confirmation from Pharmacy that all relevant close-out activities have been completed by the Pharmacy department at the trial site.

The purpose of this SOP is to ensure that the Pharmacy file is ready for archiving./closure. This SOP also describes what actions should be taken during the process of study closure or closedown visit conducted by the trial Sponsor.

The procedures for the processing of the final trial related payments are also described.

2 Who Should Use This SOP

This applies to all members of the pharmacy clinical trials from York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

The procedure should be used;

- When requested to close down a trial by the trial Sponsor.
- During the trial close-out visit by the trial Sponsor.

- When preparing the Pharmacy file for archiving.

4 Procedure(s)

Trial close-out will usually take the form of a close-out visit and the relevant member of the Pharmacy clinical trials team should follow the procedure outlined below.
In some circumstances, Pharmacy staff may be asked by the trial Sponsor to closedown the study in the absence of a Trial Monitor or Clinical Research Associate. This may include completion of a closedown checklist (provided by the trial Sponsor via post or email) which you are required to action, complete and return. In these circumstances you should comply with the request from the trial Sponsor and also follow the actions specified below, which would normally occur during the trial closedown visit. In this case, Pharmacy would assume the responsibility of performing these tasks. A copy of any completed closedown documentation should be filed with the Pharmacy trial file.

Obtain and complete the process on Pharm/F87 - Pharmacy Trial Closedown Form. If the file you are preparing for archiving has multiple files, many participants and has not had file maintenance performed within the last year. Complete Pharm/F82 – pharmacy clinical trials maintenance form in conjunction with Pharm/F87.

4.1 Final Pharmacy payments

If applicable, prior to the trial close-out visit, a member of the Pharmacy clinical trials team should prepare the final invoice for the study according to agreement in the costing template.
At the trial close-out visit, agree with the Sponsor representative what the remaining payments are for the study and confirm the invoice has been prepared by the Pharmacy clinical trials team and will be sent to our Finance department at York Teaching Hospital NHS Foundation Trust. If required by the sponsor supply a copy of the financial agreement. All other documents/invoices that maybe in the pharmacy site file must be removed for confidentially reasons. All financial correspondence/invoices must be kept in the studies electronic folder on the X:drive and a file note should be placed in the pharmacy site file detailing this.

4.2 The trial close-out visit

The trial close-out visit will be conducted by the Sponsor in the presence of a member of the Pharmacy clinical trials team at York Teaching Hospital NHS Foundation Trust. At the close-out visit the following activities should be carried out by the Sponsor representative with the support of a member of the Pharmacy clinical trials team:

- Reconciliation of the trial medication supplies or Investigational Medicinal Product. This should include a check that all IMP has been returned by patients. All IMP accountability logs must be checked for accuracy and any discrepancies accounted for.

- Check all the essential documents are in the Pharmacy file

In preparation for this a member of the Pharmacy clinical trials team is responsible for ensuring that:

- Copies of all storage temperature graphs covering the period the IMP has been stored on site are reviewed and archived centrally. A signed and dated file note should be placed in the Pharmacy trial file documenting that the temperature graphs have been reviewed and describing where these can be obtained if required. Temperature graphs should be stored in York Teaching Hospital NHS Foundation Trust and archived by the Trust periodically. It is also acceptable for the temperature graphs to be stored in the Pharmacy file itself.

- All randomisation code break envelopes (if applicable) are present in the Pharmacy file.

- Copies of all relevant correspondence are printed and filed in the relevant section of the Pharmacy file.

- All documentation is completed accurately and in full (any discrepancies in documentation and drug accountability must be accounted for and file notes written, as applicable, to describe these).

- All payments to Pharmacy have been made.

After the close-out visit, the Sponsor will write to Pharmacy to confirm that all activities required for trial close-out have been completed, or describe what actions are required by Pharmacy (i.e. if IMP discrepancies were noted during the Trial close-out visit then these will need to be satisfactorily explained). This will take the form of a final trial close-out monitoring report (usually a letter via post or email). Once confirmation of the trial close-out visit has been received from the Sponsor and all actions contained within have been completed as applicable, the report should be filed within the Pharmacy file and the following activities can take place;

- Removal or on-site destruction of trial medication supplies or Investigational Medicinal Product (if applicable) and documentation of this activity.

If no IMP discrepancies are noted during the trial close-out visit, the Sponsor representative may return IMP to the Sponsor during this visit. If IMP discrepancies are present then these must be satisfactorily explained and accepted by the Sponsor prior to return of the IMP. Returns to the Sponsor should be documented within the Pharmacy file (usually by obtaining a copy of the completed Sponsor provided returns documentation). Where IMP is to be destroyed on-site, destruction should only be conducted following written authorisation from the Sponsor. A certificate of destruction should be completed and filed within the Pharmacy trial file.

Ensure the closeout documentation provided by the sponsor is completed as well as Pharm/F87 Pharmacy Trial Closedown Form. Store within the studies pharmacy site file until the file is ready to be collected/dropped off.

4.3 Documents to be kept by Pharmacy

Prior to sending the Pharmacy file for archiving as described above, including finalising any outstanding the financial payments retain and complete the following:

1. Complete and retain Pharm/F87 Pharmacy Trial Closedown Form and keep in the “Pharmacy site files sent for archiving” folder. Ensure the member of staff taking receipt of the pharmacy site file completes their section of the form.
2. Update any relevant tracking spreadsheets or electronic records relating to the change in status of this study.

5 Related SOPs and Documents

Pharm/F87	Pharmacy Trial Closedown Form
Pharm/F82	Pharmacy clinical trials maintenance form.