York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S42

Pharmacy Financial Agreements and Invoicing

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Signature:	Signed copy held by R&D Unit
	Date:	12th March 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	1st January 2010	
2.0	4th February 2013	Change of SOP Controller. Removal of reference to the North and East Yorkshire R&D Alliance. Removal of appendix A and B as no longer frequently used. Addition of NIHR Industry costing template as source for pharmacy fees for commercial trials. Removal of references to Pharmacy Clinical Trials Administrator. Addition of Scarborough hospital as a site using this SOP.
3.0	28th October 2013	Removal of references to invoice template Pharm/T14 as this is no longer applicable.
4.0	12th April 2015	Addition of reference to new version of invoice template Pharm/T14. Removal of reference to Pharm/F29 and Pharm/F30 as these are no longer applicable. Addition of reference to Clinical Trials Pharmacy Fee Tracker.

Contents

1 Introduction, Background and Purpose

For all commercially sponsored clinical trials the Pharmacy department should be reimbursed for the work involved in the set up and running of the trial. This should be written into the Clinical trials Agreement (CTA) negotiated by the R&D Unit (see R&D/S23).

Trials sponsored by charitable, government and academic organisations may not provide payment for this work. This should be discussed as part of the trial set up and any payments for pharmacy services for the trial negotiated, if applicable, by the R&D Unit. The CTA should make clear whether or not Pharmacy Fees have been agreed with the Sponsor.

The purpose of this SOP is to ensure that the Pharmacy department receives payment of Pharmacy fees, and re-imbursement of drug costs as appropriate.

2 Who Should Use This SOP

This procedure should be followed by all members of the clinical trials team within the Pharmacy department at York and Scarborough hospitals, which form part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used when:

- Preparing a report for the R&D Unit to ensure that the correct fees are detailed (see Pharm/S41 and Pharm/F28). This may be used by the R&D Unit in the preparation of the Clinical Trials agreement (CTA).
- Agreeing Pharmacy Fees for a trial with the CRN Industry Manager or York Research & Development department.
- Preparing an invoice for a clinical trial to ensure that the invoice contains all the required Pharmacy fees.
- Recording and reconciling the payment of fees by Sponsors of clinical trials.
- Applying for Service Support costs from the Comprehensive Research Network (CRN).

4 Procedure(s)

4.1 Preparation of Fees for the Research and Development Report

Also refer to Pharm/S41 and Pharm/F28.

The Clinical Trials Manager / Pharmacist or Senior Pharmacy Technician will review the trial protocol to identify the workload and activities required for pharmacy services to the trial.

The latest version of the NIHR Industry Costing Template (available at http://www.crn.nihr.ac.uk/can-help/life-sciences-industry/setup-service/) will be

used to determine the fees required from commercial companies for the Pharmacy Services required for the trial.

Non-commercial trials must be assessed on a case by case basis depending on the funding available. An application to the CRN for Service Support Cost funding may be required. In particular, there may be funding available locally for Pharmacy services to York sponsored or co-sponsored studies and an application for these should be directed to the York Head of R&D. In these circumstances, the NIHR Industry costing template should act as a guide as to what services may be offered and the corresponding fees, however, consideration must be made as to the levels of funding available from the Sponsor.

An assessment of the fees required should be sent to the Research & Development department as part of the Pharmacy Assessment Form (Pharm/F28). Pharmacy Fees may also be agreed with the CRN Industry Manager.

The Research & Development department will incorporate these fees into the Clinical Trial Agreement. Pharmacy fees will be requested to be paid directly to Pharmacy and separated from the arrangements for the Investigator fees.

A copy of the Pharmacy payments schedule of the Clinical Trials Agreement should be obtained from the Research & Development department to be kept for reference in the Pharmacy trial file (See Pharm/S44 – Set up of Pharmacy clinical trial file).

4.2 Invoicing

Invoice requests will be raised by Pharmacy at either York or Scarborough hospital. Invoice requests may also be raised by the York Research & Development department.

An invoice request detailing the fees to be paid will be prepared using the Invoice Request Template (Pharm/T14) located on the North Yorkshire Research website (http://www.northyorksresearch.nhs.uk/), ensuring the following information is included:

- Study name
- PI
- Protocol number
- Site number
- EudraCT number
- R&D reference
- Date
- Payee name and address
- FAO including contact e-mail address
- Fee description including patient number and cost breakdown

The invoice request (Pharm/T14) should be printed off and filed in the financial information and invoices section of the individual study trial file.

The invoice will contain the agreed fees as stated on the Clinical Trial Agreement and these elements will be recovered as follows;

Set-up fee –this invoice request will be raised once the trial has received NHS permission.

Per prescription (dispensing) fees, storage fees, trial maintenance or IMP management fees – this invoice request will be raised at intervals depending on the activity of the trial. This interval will usually be 3 to 6 months.

Close down fee and other fees (as applicable) - this invoice request will be raised after the last Investigational Medicinal Product is returned to the sponsor or sent for destruction.

Re-imbursement of drug costs (as applicable) – this invoice request will be raised as those costs are incurred.

All completed invoices will be sent to the Pharmacy Finance Manager (or other delegated individual) in the Finance department at York or Scarborough hospital via email.

Note: In circumstances where Pharmacy fees/payments are included within the Investigators fees/payments, Pharmacy will request that the Research & Development department transfer the Pharmacy portion of the fees to the Pharmacy Research budget at York or Scarborough hospital.

4.3 Payment Tracking

The Finance Department at York Teaching Hospital Foundation Trust will transfer all Pharmacy fees for clinical trial work to the Pharmacy research budget.

Invoices should be raised quarterly according to the timeline set out in the 'Invoices' tab within the 'Clinical Trials Pharmacy Fee Tracker' located in X:\Clinical Trials Trackers\Finance\Finance 2014-2015.

When any invoice request is raised, the amount of the invoice will be added to the Fees Claimed tab. Paper copies of the invoice requests sent will be filed in the financial information and invoices section of the individual study trial file.

A copy of the Pharmacy research budget report is received monthly by the Clinical trials Manager. This should be reviewed for payments from trial sponsors and the CRN and reconciled against the 'Fees Claimed' tab of the 'Clinical Trials Pharmacy Fee Tracker'. Additionally the individual study trial tab should be located and updated to reflect which fees have been paid.

5 Outstanding or missing payments should be communicated to the Finance Department (Pharmacy Finance Manager or other delegated individual) on a regular basis to ensure payment is made by the Trial Sponsor.

6 Related SOPs and Documents

Pharm/S41	Pharmacy Trial Assessment and Confirmation of Readines
Pharm/F28	Pharmacy Assessment Form
Pharm/S44	Set up of Pharmacy Clinical Trial File