York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S42

Pharmacy Financial Agreement 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/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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	Caroline Savage
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Signature:	
	Date:	5th July 2022
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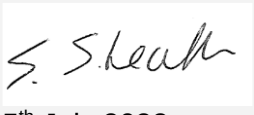
	Signature:	
	Date:	5th July 2022

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 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3.0	28th October 2013	Removal of references to invoice template Pharm/T14 as this is no longer applicable.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 Removal of reference to Pharm/F29 and Pharm/F30 as these are no longer applicable.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.
5.0	8th March 2019	Change of author. Change of link to R&D website
6.0	26th July 2022	Change of author. Adjustments to invoicing process, links updated.

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 for any drug costs as appropriate.

2 Who Should Use This SOP

This procedure should be followed by all members of the pharmacy clinical trials team at York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used when:

- Agreeing Pharmacy fees for a trial.
- Preparing an invoice for a clinical trial to ensure that all required Pharmacy fees are claimed for.
- Checking Sponsors invoice requests against the fees we believe we are owed.
- Liaising with Sponsors and the finance department in relation to pharmacy invoices.
- Recording and reconciling the payment of fees by Sponsors of clinical trials.

4 Procedure(s)

4.1 Reviewing costing templates and financial agreements

During the set up process of a pharmacy related clinical trial the RDFs will issue pharmacy with funding documentation – if applicable (most non-commercial studies will not have any funds available for the pharmacy delivery of the trial)

Below are two types of costing templates which the Pharmacy Clinical Trials Manager or Senior Pharmacy Technician will review against the trial protocol to identify the workload and activities required from pharmacy to run the trial and confirm whether the proposed fees accurately reflect these services. If there are any issues then these must be fed back to the RDFs for resolution with the sponsor.

Commercial studies - the NIHR Industry Costing Template - a web-based interactive Costing Tool (iCT) that provides a framework for transparent cost display and calculation to support swift local site budget negotiations when planning commercial trials in the NHS.

Portfolio studies - SoECAT - a cost attribution template designed to support correct cost attribution at application for Research Cost funding to ensure that full site level Research Costs are recovered.

Non-commercial trials must be assessed on a case by case basis; if additional funding is required and needs to be obtained to run the study, this must be brought to the attention of R&D to see if the funds can be covered. If it is a Trust sponsored/co-sponsored study, 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.

Once all the fees are agreed upon, the R&D department will incorporate these into the Clinical Trial Agreement. Pharmacy fees should be requested to be paid directly to Pharmacy and separated from the arrangements for the Investigator fees if possible.

A copy of the Clinical Trials Agreement should be obtained from the R&D department once the study is open to recruitment. It is to be kept in the trial's own dedicated electronic folder on the x:drive under the sub-folder 'Clinical Trial Agreements & Finance'.

4.2 Invoicing

There are three ways in which pharmacy fees are claimed:

- Sponsor sends us an invoice – either direct to the joint mailbox or via R&D.
- Pharmacy fees are built into all the fees paid directly to R&D – care should be taken as issues may arise if we try to claim for them separately and R&D has already received the fees.
- We invoice the sponsor for our pharmacy services – we create an invoice according to the financial agreement and have it checked by a CRA before sending it to their finance department via our finance department.

  If a Sponsor provides an invoice proposal for the fees that they expect to pay for a certain time period e.g. every quarter; these should be checked against the PSF for accuracy and the sponsor contacted for corrections if necessary. Once resolved/if there are no issues, a billing request should be drafted up based on this proposal.

  If no proposal is provided, use information from the PSF and trial correspondence to help create an accurate billing request.

  If the invoice request is not based on a sponsor proposal, a copy should be sent to the sponsor/trial monitor to gain their agreement on the fees. If the request is rejected, any desired adjustments/explanations should be made and approved before proceeding.

  The 'Study Fees and Invoices Tracker' spreadsheet on the X: Drive (Clinical Trials/Finance) is used to track exactly what has been claimed for on previous invoices and to help complete a billing request. As you are checking an invoice provided by a sponsor or preparing to generate your own billing request, update the latest entry for the trial you are working on by selecting the trial's specific tab.

Preparing a billing request:

Requests should provide a basic breakdown of the fees that a sponsor is expected to pay for a set period of time, and should be prepared using the Pharmacy Billing Request Template (Pharm/T14) located on the York and Scarborough Teaching Hospitals NHS Foundation Trust Research & Development Unit website (https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/pharmacy-sops-forms-and-templates/).

Details required on the invoice vary from sponsor to sponsor, but as a general rule the following information should be included:

At the top of the request:

- The study name
- Your name and the clinical trials address/extension
- The date
- Customer/Sponsor name
- FAO including contact email address
- Payee name and address

In each 'description' entry (maximum 230 characters each):

- The study name
- Site/Site number
- PI
- R&D reference
- EudraCT number
- A short fee description

Quantity – the number of instances being claimed for (this will depend on the type of fee/unit) e.g. 7 if claiming for 7 months of IMP.

Unit – the cost outlined in the Clinical Trial Agreement. This may be per instance, per hour, per month etc.

VAT – VAT is generally added on for every clinical trial and follows the going rate (20%). Some sponsors may be exempt from paying this due to their country of origin; this should be confirmed with them before any billing requests are sent to be raised.

Information about what fees can be claimed for and the sponsor's address/payment details can be found in the 'financial arrangements' section of the study's Clinical Trial Agreement, alongside any additional information that may be required on the invoice e.g. protocol number.

Invoice requests must only cover agreed upon fees that are clearly stated in the Clinical Trial Agreement, such as the following;

- **Set-up fee** – a one-time fee to be raised at the start of the trial once the study is open to recruitment.
- **Per prescription fees (dispensing, accountability etc.), storage fees, trial maintenance or IMP management fees** – to be raised at intervals

depending on the activity of the trial. This interval will usually be 3 to 6 months.

- **Close down/miscellaneous fees e.g. time spent updating SOPs due to a substantial amendment (as applicable)** - to be raised after the last Investigational Medicinal Product has been returned to the sponsor or sent for destruction.
- **Re-imbursement of drug costs (as applicable)** – to be raised as these costs are incurred/alongside dispensing fees.

All completed billing requests will be sent to the Pharmacy Finance Manager (or other delegated individual) based in the Trust's Finance department via email. These emails should clearly state the name of the trial and the payee, and finance will respond with a copy of the invoice once it has been raised.

Note: In circumstances where Pharmacy fees/payments are included within the Investigators fees/payments, invoice requests should be emailed to the R&D department instead, asking for the Pharmacy portion of the fees to be transferred to the Pharmacy Research budget.

Sponsor invoice requests, completed billing requests and finance generated invoices should be saved on the X: Drive (Clinical Trials/Finance/Current and Raised Invoices) in a sub-folder bearing the trial name.

Any emails relating to finance should be relocated from the joint mailbox to a dedicated 'Invoicing' folder within the trial's Outlook correspondence.

4.3 Payment and Tracking

Once an invoice has been sent to the finance team, its details should be entered into the 'Clinical Trials Yearly Finance Tracker' spreadsheet on the X: Drive (Clinical Trials/Finance), documenting the date that it has been sent to be raised. This should again be updated with the actual date raised once this has been confirmed by the finance team.

Once a month, the finance team will check for payments and update the Yearly Finance Tracker accordingly.

All payments for pharmacy clinical trials services/activities will be paid into the Pharmacy Research budget by the Finance department at York and Scarborough Teaching Hospitals Foundation Trust.

Outstanding or missing payments should be communicated to the Finance Department (Pharmacy Finance Manager or other delegated individual) on a regular basis to ensure that payments are made by the Trial Sponsors.

5 Related SOPs and Documents

Pharm/T14	Pharmacy Billing Request
Pharm/S44	The Pharmacy Clinical Trial File