York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S79

Receipt and review of amendments 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	Pharm/S79
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Author:	Rachel Spooner
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	19th September 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	11th September 2024

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	Reviewers	Details of significant changes
1.0	22nd November 2013		Introduction of amendment checklist Pharm/F106 & Red, Amber & Green light amendment letters are now provided as separate templates (Pharm/T44, Pharm/T45 & Pharm/T46). Other minor process changes and clarifications.
2.0	19th January 2016		
3.0	24th May 2018		Change of author. Changes to process and the relevant approvals
4.0	25th February 2021		Change of author. Change of link to R&D website. Changes to process and updates on who can process amendment types. Removal of repeated information. Updated SOP to reflect changes in the updated version of Pharm/F94.
5.0	9th October 2024	Rachel Spooner	Change of author. Minor updates. Change of location of storage of amendment paperwork and removal of reference to amendment whiteboard.

Contents

1 Introduction, Background and Purpose

All clinical trials may be subject to amendments. Amendments may include a change to the current protocol or other documents.

There are 2 types of amendments Substantial and Non-Substantial:

Substantial: an amendment to the terms of the application, or to the protocol or any other supporting documentation which is likely to affect the safety or mental integrity of participants, the scientific value of the study, the conduct or management of the study or the quality or safety of any IMP in the trial.

Non-Substantial (minor): changes to the details of a trial that are administrative. Amendments which relate to CTIMPs must be approved by pharmacy prior to implementation with-in the Trust.

This SOP describes the process of handling amendments within the pharmacy department.

2 Who Should Use This SOP

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

3 When this SOP Should be Used

This SOP should be used upon receipt of an amendment to a clinical trial within pharmacy.

4 Procedure(s)

This SOP should be used in conjunction with Pharm/F94 –Receipt and Review of Amendments in pharmacy Form.

Upon notification of an amendment (usually received into the pharmacy clinical trials joint email mailbox) a Clinical Trials Pharmacy Technician will initially assess the amendment, to decipher who is the most appropriate member of the team to process the amendment.

If the amendment requires **no** pharmacy related changes and does not impact directly on clinical aspects of the trial, this can be allocated to a Clinical Trials Senior Assistant to process. All amendments that require changes to pharmacy related documents or procedures including amendments which require changes provided from other pharmacy services must be processed by a Clinical Trials Pharmacy Technician.

The appointed member of staff will begin to process the amendment. The details of the amendment must be tracked on the amendment spreadsheet kept in clinical trials trackers section on the pharmacy clinical trials x-drive. It is essential this spreadsheet is maintained to allow for continuity and audit data collection.

All documents issued with each amendment will be saved electronically to the x-drive/ trial name/ amendments/ amendment number and the pharmacy related documents will be printed and attached to the Receipt and Review of amendments in Pharmacy Form (Pharm/F94). Whilst amendment documents are not in use (prior to implementation) they should be stored in the amendment folder in the clinical trials office. This is so anyone can pick up from where the last person finished as some amendments may take a long period of time to implement. The Receipt and Review of amendments in Pharmacy Form (Pharm/F94) must be updated regularly after each new development with an amendment so everyone is aware of which stage the amendment is at.

The amendment process is split into 4 stages documented below.
The process should be followed in conjunction with the Receipt and Review of amendments in Pharmacy Form (Pharm/F94)

4.1 Stage 1– Pharmacy Feasibility

The person processing the amendment will complete Stage 1 – Pharmacy Feasibility Including:-

- **Amendment received from whom and their job title if applicable** – this will either be the sponsor or the R&D department. If it is the R&D department, record the name and job title of the person issuing the amendment.
- **The HRA categorisation** – this can be found on the HRA email sent with the amendment notification or often in the original amendment email received – details of the categorisation types can be found on form Pharm/F94.
- **The Amendment Type** – this can be found on the HRA email sent with the amendment notification and is usually substantial or non-substantial.
- **Approvals** – the dates of each approval (if not applicable write N/A). The amendment tool issued with each individual amendment will detail which regulatory approvals are required. Check that each approval corresponds to the correct amendment number and save and print the approvals. Please note that approvals may not have been granted yet but Pharmacy No Objections can still be issued when site feasibility is confirmed. If an extension to the 35 day no-objection period is required, this should be arranged with research team and the sponsor.
- **Documents received** – on the form, indicate which documentation has been received along with the amendment notice. Save the relevant pharmacy documentation to the x-drive in the amendment section for the trial and print copies of the documents relevant to pharmacy. Printed copies should be stored alongside Pharm/F94 in the clinical trials office until implementation.
- **Other departments within pharmacy that maybe involved in the amendment** :
    - **Aseptic involvement**– if the amendment involves new treatment arms, or changes to aseptic products used (e.g. new IB's) the aseptic department will need to review the amendment and agree that they are able to support the changes and make changes to their worksheets or other documentation.
    - **Oncology Satellite involvement** -If there are changes to the protocol version, blood tests, new treatment arms etc for studies involving ChemoCare then the oncology satellite department must review the amendment details and agree that they can support the changes. They will need to update the ChemoCare prescriptions as part of the amendment.

  The work required does not need to be completed by the above-mentioned pharmacy departments within the 35 day no-objections period, however we must receive email confirmation from a member of each team

agreeing they can support the amendment. Attach the confirming e-mail to the Receipt and Review of amendments in Pharmacy Form (Pharm/F94). If the amendment does not directly affect pharmacy and the protocol version is not changed then the amendment does not need to be reviewed by the oncology satellite team.

- **Any additional cost to pharmacy** – if the amendment involves any additional costs to pharmacy, this should be documented and Research Governance informed as this may delay the amendment as this stage cannot be completed until it has been clarified who is funding the cost.

Once all the above sections have been completed, circle if Pharmacy are happy to proceed with the amendment with the information available at this stage. Sign, print and date the completed by section for the Pharmacy Feasibility.

Obtain a pharmacist signature if the amendment involves drug and/or clinical treatment changes.

Once all the above have been completed, a Pharmacy No-Objections/Objection e-mail can be sent to research governance and the research team member who is dealing with the amendment. A copy of this e-mail must be printed and attached to the Receipt and Review of amendments in Pharmacy Form (Pharm/F94) and stored electronically. Update the final section on the pharmacy feasibility section of the form.

4.2 Stage 2 – Pharmacy Review of changes required

This section needs to be fully completed before an implementation date can be organised.

The person processing the amendment will complete the following: -

- **Date of capability and capacity received from R&D** – this is an email that is sent from the R&D Governance team once they have received confirmation from all support areas and the PI that the amendment can be processed. This constitutes an instruction to continue with the processing and implementation of the amendment in line with all involved. This may be delayed if approvals are still pending but all work can still be completed whilst waiting for this.
- **Documents which require amendment(s)** – highlight the pharmacy documents which will need to be amended as a result of the amendment and record the date that these updates have been completed. Amended documents will be reviewed and checked following the relevant SOPs related to the individual document.
- **Is additional sponsor training required** – tick 'yes' if pharmacy staff will need to receive training and complete any training logs provided by the sponsor.
- **Pharmacy support departments (Aseptics and oncology satellite)** – once all the relevant departments (if applicable) have confirmed completion of their changes to their documentation/procedures, attach the e-mail confirmation to the form or obtain a signature in the dedicated section of the form.

Sign, print and date the completed by section for the Pharmacy Review of changes.

4.3 Stage 3 –Readiness- Planning for implementation.

Stage 3 will be completed once Stage 2 has been completed and signed as complete. All relevant approvals must have been received and continuing capacity and capability has been issued by R&D. At this point an implementation date can be set.

The person processing the amendment will complete the following: -

- **Date the in-house pharmacy training log has been signed by all the required pharmacy personnel** – this is only required if the amendment involves a new protocol, IB or SmPC, or the amendment has resulted in updates to central pharmacy documentation, such as trial instructions.
- **Date the sponsor training has been completed by all the required pharmacy personnel** – if applicable.
- **Date all amended documents have been reviewed and approved** – this will include aseptic worksheets, ChemoCare prescriptions, trial instructions and labels etc.
- **Agreed implementation date** – email the research team and agree a date for implementation.
- **Name and job title of research staff member agreeing the implementation date**

Sign, print and date the completed by section for the Readiness- Planning for implementation.
The amendment tracker spreadsheet on the pharmacy clinical trials X:Drive will be amended to reflect any set date.

4.4 Stage 4 – Implementation

Stage 4 will be completed on the day of implementation.

The person processing the amendment will complete the following: -

- **Date of implementation**
- **Date new documents filed in their relevant section of the pharmacy site file** – regulatory approvals, amendment form (Pharm/F94) and any other relevant pharmacy documentation that does not have a specific section in the pharmacy site file, file in a plastic wallet in the amendment section of the PSF. Ensure all documents are moved in to the current electronic folders in the study's section of the X:Drive to reflect the physical PSF. All new trial instructions should also be scanned to the x-drive before physically filing.
- **Amendment log updated in the pharmacy site file** – tick when completed.
- **Date old documents superseded** – All previous versions of documents that require superseding must be stamped 'superseded' with the date and initials of the person superseding and filed in the superseded section of the PSF. Ensure these documents are moved to the superseded section of the electronic study folder on the X:Drive to reflect the physical PSF.
- **Inform pharmacy oncology satellite/aseptic unit that we are working to new version** – if applicable
- **Amendment tracker spreadsheet updated**

Sign, print and date the completed by section for implementation.

Store the completed Pharm/F94 – Receipt and Review of Amendments in Pharmacy Form at the front of the plastic wallet which contains the amendment paperwork in the amendment section of the PSF.

Amendments should be stored in chronological order to reflect the order on the amendment log.

5 Related SOPs and Documents

Pharm/F94 – Receipt and Review of Amendments in Pharmacy Form