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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Approved by:	Name/Position:	Jax Westmoreland, Principal Pharmacist, Clinical Trials and Research
	Signature:	Signed copy held by R&D Unit
	Date:	26th April 2018
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	Signature:	Signed copy held by R&D Unit
	Date:	26th April 2018

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	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

Contents

1 Introduction, Background and Purpose

All clinical trials where medicines classed as Investigational Medicinal Products (IMPs) are involved 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 Teaching Hospital 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 either by letter or email the clinical trials manger will appoint a member of staff to process the amendment. The amendment will be added to whiteboard in the pharmacy clinical trials office at York along with the name of the person appointed to process it.

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 kept in a folder with the Receipt and Review of amendments in Pharmacy Form (Pharm/F94).
The amendment process is split into 4 stages:

Stage 1: Pharmacy Feasibility
This has to be completed within 35 days of receipt of notification of amendment which is issued to the Trust by the sponsor. Relevant approvals may not have been received at this point and pharmacy are assessing the amendment and ensuring that they are able to proceed with it. Stage 1 is issued to R&D Governance.

Stage 2: Pharmacy Authorisation
Pharmacy authorisation is issued once any necessary changes have been made to current documentation. These changes may involve the satellite unit and/or aseptics. Stage 2 is issued to the relevant research team.

Stage 3: Pharmacy Readiness
Pharmacy readiness is issued once amended documentation has been reviewed and approved and pharmacy are ready to agree an implementation date with the research team. Stage 3 is issued to the relevant research team.

Stage 4: Pharmacy Green Light
The pharmacy green light is issued once the amendment has been implemented and serves to confirm that all new documentation has been added to the pharmacy site file and that older versions have been superseded. Stage 4 is issued to the relevant research team.

The person appointed to process the amendment will complete the front page with the following:-

- Short trial name/number and long title
- EudraCT number
- R&D reference
- Sponsor
- Principal Investigator
- Name of Lead Research Nurse
- Name of CTA
- Site
- Study Phase
- Date of Notification of the Amendment
- Amendment Number
- Speciality
- Indication
- Date added to Amendment Tracker Spreadsheet

4.1 Stage 1

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 we need record the name and the job title of the person issuing the amendment
- **The HRA categorisation** – this can be found on the HRA email sent with the amendment notification – 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), check that each approval corresponds to the correct amendment number. Save and print the approvals. Please note that approvals may not have granted as yet but stage 1 can still be issued.
- **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 in the dedicated amendment area of the clinical trial dispensary.

- **Aseptic involvement** – if the amendment involves new treatment arms, or changes to aseptic products the aseptic unit will need to review the amendment and agree that they are able to support the changes. This agreement can be in the form of an email and must be received within the 35 day period. The changes do not have to be made within this time period.
- **Satellite involvement** - if the amendment does not directly affect pharmacy and the protocol version is not changed then the amendment does not need to reviewed by the satellite unit. If there are changes to the protocol version, blood tests, new treatment arms etc. then the satellite unit must review it and agree that they can support the changes. This agreement can be in the form of an email and must be received before the 35 day period. The changes do not have to be made within this time period.
- **Any additional cost to pharmacy** – if the amendment involves any additional costs to pharmacy, this should be documented and R&D Governance informed as this may delay the amendment as this stage cannot be completed until it has been clarified who is funding the cost.

Complete the general overview of the amendment or attach a copy of the summary of changes to the form.

Sign the completed by section of stage 1. The pharmacy clinical trials manager or principal pharmacist will then sign to confirm that they are happy for us to continue with the amendment or that we cannot go ahead with the amendment and email the form to R&D Governance. The whiteboard in the pharmacy clinical trials office at York will be amended to reflect that stage 1 has been completed.

4.2 Stage 2 – Pharmacy Authorisation

Stage 2 will be completed as soon as Stage 1 has been authorised by the pharmacy clinical trial manager or principal pharmacist.

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 which is sent once they have received confirmation from all support areas and the PI that the amendment can be processed and constitutes an instruction to continuing processing and implantation of the amendment.
  Stage 2 may be completed without receiving this email but stage 3 may not.
- **Documents which require amendment(s)** – highlight the documents will need to be amended and record the date that this amendment has been undertaken. Amended documents will not yet be reviewed and approved.
- **Is additional sponsor training required** – tick yes if pharmacy staff will need to receive training and complete any training logs provided by the sponsor.
- **Aseptic completion of changes** – once all documents have been amended (but not necessarily approved) aseptics to sign or attach a copy of an email confirming this.
- **Satellite completion of changes** - once all documents have been amended (but not necessarily approved) satellite to sign or attach a copy of an email confirming this.
- **Clinical trials pharmacist approval (if applicable)** – all substantial amendments and non-substantial amendments involving any changes to pharmacy will need to be signed off by the pharmacist.

Sign the completed by section of stage 2.
The pharmacy clinical trials manager or principal pharmacist will then review the form, sign to confirm that stage 2 has been completed and email the form to the relevant research team CTA.
The whiteboard in the pharmacy clinical trials office at York will amended to reflect that stage 2 has been completed.

4.3 Stage 3 – Pharmacy Readiness

Stage 3 will be completed as soon as Stage 2 has been reviewed and authorised by the pharmacy clinical trial manager or principal pharmacist and once all relevant approvals have been received and that continuing capacity and capability has been issued by R&D.

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 trial instructions have been amended.
- **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, labels and batches of pre-printed 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 the completed by section of stage 3.
The pharmacy clinical trials manager or principal pharmacist will then sign to confirm that stage 3 has been completed and will email the form to the relevant research team CTA.
The whiteboard in the pharmacy clinical trials office at York will be amended to reflect that stage 3 has been completed.

4.4 Stage 4 – Pharmacy Greenlight

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 and any other documentation that does not have a specific section in the pharmacy site file, file in a plastic wallet marked with the amendment number in section 23 of the pharmacy site file.
- **Amendment log updated in the pharmacy site file** – tick when completed
- **Date old documents superceded** – All previous versions must be stamped superseded on every page with the date and initials of the person superseding.

- **Inform pharmacy satellite/aseptic unit that we are working to new version** – if applicable
- **Amendment tracker spreadsheet and whiteboard updated**

5 Related SOPs and Documents

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