York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S46

Receiving Clinical Trials Materials and Investigational Medicinal Products into Pharmacy Stores

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S46
Version Number:	5.0
Author:	Richard Evans
Implementation date of current version:	28th October 2015

Approved by:	Name/Position:	Jax Westmoreland, Principal Pharmacist, Clinical Trials and Research
	Signature:	Signed copy held by R&D Unit
	Date:	30th September 2015
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	30th September 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	7th July 2009	
2.0	1st January 2010	Pharmacy SOP put into revised template. Mobile number removed. Minor revisions.
3.0	2nd July 2012	Change of SOP Controller. Removal of references to the North and East Yorkshire Alliance. Revisions relating to receipt of frozen products and update of contact numbers for Clinical Trials team
4.0	6th September 2013	Changed to include Scarborough Hospital as a site using this SOP. Inclusion of reference to the MHRA Good Clinical Practice Guide. More detailed procedures describing receipt of IMP for individual trials and what can be found in the Pharmacy Trial Instructions.
5.0	28th October 2015	Minor revisions. Removal of references to Pharm/T25 (as this template is due to be replaced) & the Pharmacy distribution list (as this is no longer in use).

Contents

1 Introduction, Background and Purpose

The purpose of this SOP is to ensure that when clinical trial materials and Investigational Medicinal Product (IMP) are received into Pharmacy stores the correct procedure is followed. It also describes the documentation required to ensure an audit trail for the receipt of goods into pharmacy stores for use in clinical trials.

The procedures for receiving IMP into Pharmacy stores are constant and should be followed as detailed in this SOP. However, the procedures for receiving IMP for each individual trial will vary depending upon the trial arrangements mandated by the Sponsor. This SOP therefore also describes where the procedures for receipt of IMP for each individual trial can be found and what activities constitute the key elements of this process.

It is important that the process of receipt of IMP for a clinical trial complies with current UK legislation and guidance. The Medicines and Healthcare products Regulatory Agency (MHRA) have produced a Good Clinical Practice guide which is useful in this respect and has been used to support production of this SOP. Section 4.1 of this SOP lists the Key elements involved in the process of receiving in IMP for an individual trial, however, the grey guide provides information on drug accountability in line with the risk-adapted approach (Section 6.13.2) and indicates circumstances under which the level of accountability (and requirement for shipping receipt records) needed may vary, in line with the IMP risk category of a trial, as determined by the Trial Sponsor. This means that the procedures detailed in Section 4.1 may be amended or reduced in line with this, as advised by the Trial Sponsor. If there is any doubt as to what accountability records or documentation is required for a particular trial, the Trial Sponsor should be contacted.

The risks of not following this SOP include;

- Failure to check the receipt of goods into Pharmacy stores resulting in an incorrect audit trail of drugs received.
- Incorrect compliance with drug accountability required for the trial.
- Drugs received being stored in incorrect temperature conditions.
- Investigational Medicinal Products (IMP) being wasted.
- Cancellation of patients' appointments.

In addition, the incorrect physical handling of drugs received into pharmacy stores can result in a member of staff becoming at risk to back or other muscular problems.

2 Who Should Use This SOP

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

3 When this SOP Should be Used

This SOP should be used whenever clinical trial materials or IMPs are received by Pharmacy Stores staff, and when the Pharmacy clinical trials team are conducting the process of receiving IMP for each individual trial.
The sections of this SOP relating to frozen storage conditions will only be applicable in those circumstances where Pharmacy has responsibility for the storage of a frozen IMP.

4 Procedure(s)

Goods should only be received into stores by trained members of Pharmacy staff. Trainee/student members of staff can receive goods into the department only under the supervision of a trained member of Pharmacy stores staff.

1. Check that the address on the delivery note is correct i.e. that the delivery is for this hospital and that the correct quantity of boxes have been delivered.

2. Sign the delivery driver's documentation.

3. Check the addressee on the address label to identify whether the delivery is for clinical trials. Clinical trials materials should be addressed to the clinical trials team or a current member of the team.

4. If the supplies are incorrectly labelled then communicate this to a member of the clinical trials team. The clinical trials team will write to the supplier or trial sponsor in these circumstances to arrange for them to change the addressee details.

5. Check the storage conditions of the goods received i.e. are the products for room temperature storage (15^{o}C to 25^{o}C/30°C), refrigerated storage (2^{o}C to 8^{o}C) or frozen storage (-20ºC or below). Deliveries requiring refrigeration or frozen storage will be marked on the outside of the box or indicated by the presence of a thermometer symbol (those requiring frozen storage may state the product is stored under dry ice). **When a product that requires refrigerated or frozen storage is received into stores it must be dealt with immediately.**

6. Complete form Pharm/F35 (Stores Receipt Form) and follow the instructions that are included on this.

7. **For deliveries requiring frozen storage**, contact a member of the clinical trials team by ringing ext: 1684/4522 (Ext:6230 in Scarborough) to make them aware of the delivery. State that it is a delivery requiring frozen storage. A member of the clinical trials team will attend Pharmacy stores to collect the delivery immediately. The completed Stores Receipt Form (Pharm/F35) should be left with the delivery for collection by the clinical trials staff.

8. **For deliveries requiring frozen storage where a member of the clinical trials team is not available (and you are confident the contents are stored under dry ice)**; DO NOT unpack the box, take the

delivery to the clinical trials dispensary and place the box and delivery documentation (including Stores Receipt Form) on the bench. Send an email to all members of the clinical rials team to confirm receipt of supplies and their location. Continue to try to contact the clinical trials team until you are satisfied that they are aware of the delivery. Once aware of the delivery, the clinical trials team will proceed to deal with the delivery contents.

9. **For Health and Safety reasons, under no circumstances must boxes containing products on Dry Ice (for frozen storage) be unpacked by members of Pharmacy Stores.**

10. **For deliveries requiring frozen storage where a member of the clinical trials team is not available (and the contents are NOT stored under dry ice)**; unpack the box, and store the contents under the correct frozen conditions in the clinical trials freezer. Take the completed Stores Receipt Form in this instance and place it in the clinical trials office. Send an email to all members of the clinical trials team to confirm receipt of supplies **and their location**. Continue to try to contact the clinical trials team until you are satisfied that they are aware of the delivery. Once aware of the delivery, the clinical trials team will proceed to deal with the delivery. Please note: a clinical trials freezer will be provided for use during the conduct of trials requiring IMP storage under these conditions.

11. **For deliveries requiring refrigeration**, Contact a member of the clinical trials team by ringing ext: 1684/4522 (Ext:6230 in Scarborough) to make them aware of the delivery. State that it is a delivery requiring refrigeration. A member of the clinical trials team will attend Pharmacy stores to collect the delivery immediately. The completed Stores Receipt Form (Pharm/F35) should be left with the delivery for collection by the Clinical Trials staff.

12. A member of the clinical trials team will pick up the Stores Receipt Form and associated delivery and proceed to follow the procedures for receiving supplies detailed in the trial instructions for the relevant clinical trial (See Pharm/T25 – Pharmacy Trial Instructions). See Section 4.1 for details of what this process will entail. Please note: the Stores Receipt Form should be retained with the trial delivery paperwork to ensure the delivery audit trail is maintained. Both should be filed in the relevant Pharmacy file for the study.

13. **For deliveries requiring refrigeration where a member of the clinical trials team is not available**; unpack the box, place the contents (clearly marked as clinical trials stock) and delivery documentation in the Pharmacy cold-room (quarantine fridge in Scarborough). Take the completed Stores Receipt Form in this instance and place it in the clinical trials office. Send an email to all members of the clinical trials team to confirm receipt of supplies and their location.

14. **Under no circumstances must the IMP be left in the coldroom in it's delivery packaging as the temperature of the supplies may fall below 2ºC due to the presence of ice packs.**

15. **For deliveries requiring room temperature storage**, store the delivery box in stores awaiting collection. Place the completed Stores Receipt Form on top of the delivery box.

16. Contact a member of the clinical trials team on ext: 1684/4522 (Ext: 6230 in Scarborough) to inform them of a room temperature delivery. In the case of not being able to contact anyone from clinical trials, leave the delivery and documentation on the bench in stores. Place the Stores Receipt Form in the clinical trials office. Send an email to all members of the clinical trials team to confirm receipt of supplies.

17. A member of the clinical trials team will attend stores and pick up the delivery and return to the clinical trials dispensary. They will then follow the procedures for receiving supplies detailed in the Pharmacy trial instructions for the relevant clinical trial.

18. When receiving large volumes of goods into stores ensure the correct procedures are followed (refer to the Trust Manual Handling and Back Care policy and 'Operation of palette truck in pharmacy stores' procedure).

19. FOR CLINICAL TRIALS STAFF: When following the Pharmacy trial instructions for receipt of the trial supplies, care must be taken to ensure that all parts of the procedure are followed. This is a particularly important step in the process of ensuring drug accountability records are maintained accurately. Failure to record the delivery received on a drug accountability record will lead to inaccurate drug accountability and non compliance with Good Clinical Practice.

4.1 Procedures for receiving IMP for an individual trial – The Pharmacy Trial Instructions

Once an IMP delivery has been collected from Stores by a member of the Pharmacy clinical trials team, they will proceed to follow the authorised procedures for receipt of supplies as detailed in the Pharmacy Trial Instructions relevant to that trial.

These Trial Instructions are written by a member of the Pharmacy clinical trials team prior to the start of the study using information from the Protocol, Pharmacy manual or that provided by the Trial Sponsor.

There are key elements to this receiving in process that will be followed by the member of the clinical trials team. These are listed below to indicate what the process will involve;

- Checking of supplies against the packing list.

- Confirming receipt of the supplies to the Trial Sponsor or supplier including details on how to do this through Interactive Voice Recognition Systems (IVRS) or Interactive Web-based Recognition Systems (IWRS) systems if appropriate.

- Instructions on what to do if supplies are damaged or missing.

- Checking of any temperature monitoring devices in the package and how to return the information to the sponsor (if necessary).

- Checking of the supplies against quality documentation e.g. Certificate of analysis (CofA) and/or Qualified Person (QP) certificate of release (if applicable).

- Instructions on what to do if the above quality documentation is missing or incorrect.

- Instructions in how to complete accountability records to document the arrival of IMP.

- Instructions on where to store the delivery documentation.

- Instructions on where and how to store the IMP that has arrived within the Pharmacy or clinical trials dispensary.

- Details of any labelling that is required upon receipt of IMP.

- Any other information as deemed relevant to this process.

As noted within Section 1 of this SOP the above requirements will vary for each trial and will be different according to the IMP risk category of the trial.

5 Related SOPs and Documents

Pharm/F35 – Stores Receipt Form

Operation of Palette Truck in Pharmacy Procedure

Trust Manual Handling and Back Care policy

MHRA Good Clinical Practice Guide 2012