York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S46

Receiving Clinical Trials Materials

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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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	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).
6.0	18th June 2018		Change of author. No other changes necessary
7.0	13th August 2020		Change of author. Change of link to R&D website. Removal of Stores Receipt procedure. Addition of the procedure for receiving Clinical Trials Hospital stock and more detail added to the procedure for receiving Trial-specific IMP. Removal of references to Pharm/F35 (as this form is due to be removed)
8.0	18th January 2024	Rachel Spooner	Change of author. Updated to reflect move from JAC to CMM.

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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 and clinical trials, the correct procedure is followed.

The procedures for receiving IMP into Pharmacy stores are constant and should be followed as detailed in their 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. The procedure for receiving in hospital stock into Pharmacy clinical trials is constant and should be followed as detailed in this SOP.

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;

- 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 Teaching Hospitals 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 and hospital stock 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 4.0 Procedure for receiving clinical trials materials and IMP in to Pharmacy Stores

The Pharmacy Stores team should follow the departmental SOPs when receiving stock in to Stores. The procedure to follow when receiving Clinical Trials Materials into stores is explained in the departmental SOPs, and states that when a clinical trial material or IMP is received, a member of stores staff should immediately inform the pharmacy Clinical Trials team. It is the responsibility of the pharmacy clinical trials team to act upon the information provided by the stores member of staff in a timely manner.

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.

4.2 Procedure for receiving hospital stock in to clinical trials

Once a delivery of hospital stock has been collected from Stores by a member of the Clinical Trials team, the following procedure for unpacking, checking and accepting the delivery should be followed:

- Immediately unpack the shipment box and remove any delivery paperwork from the box.
- If no delivery paperwork is present, speak to the Pharmacy Stores staff to check they do not have this paperwork.
- Ensure that any specific temperature conditions are maintained:
    - If the item is an ambient item, no specific temperature monitoring is sent with the delivery. Therefore, proceed to unpack the stock from the box.
    - If the item is a fridge item, any instructions included in the shipment should be followed regarding temperature monitoring, and in all cases, the cold chain should be maintained.
    - For any other stock where specific storage conditions are required, all instructions included in the shipment should be followed to ensure the stock is stored in the correct conditions at all times.
- Check that the hospital stock is intended to be used by Clinical Trials using the ‘Order number reference’ on the delivery note. All clinical trials Order numbers begin with ‘YCT’. If the order number does not begin with ‘YCT’, take the box back to stores and inform the team that the delivery is not intended for clinical trials.
- Check that the product type, strength, form, and quantity match that on the delivery note. Ensure that the batch number and expiry date on the product(s) delivered match that on the delivery note.
- Ensure that the product delivered has a suitable expiry date, is not damaged and is suitable for use.
- Log on to CMM and use the ‘ODeliv’ function within the ‘Ordering and Invoicing’ section to accept the delivery.

- In the ‘ODeliv’ function, start to enter the ‘YCT’ number and select the delivery with the correct ‘Order number’.
- Confirm that the products on the order have been delivered and enter the batch number(s) and expiry date(s) on the ‘Batch number’ screen.
- Confirm that the products have been delivered and print the CMM confirmation report.
- Sign and date the delivery note to confirm the delivery has been accepted on to CMM
- Copy this delivery note and place the original document in to the ‘Invoicing’ tray in Pharmacy Stores to be sent to the Invoicing team
- Place the product in the appropriate location within the Clinical Trials dispensary, ensuring that the current stock on the shelf is rotated according to their expiry dates
- Check the pharmacy trial instructions to see if the sponsor requires the stock to be logged on to an accountability log not all studies will require this.
- File the copy of the delivery note, CMM report and the original ‘hospital stock order form’ together in the ‘Monthly stock checks and hospital stock ordering’ folder which is kept in the Clinical Trials office.

5 Related SOPs and Documents

MHRA Good Clinical Practice Guide 2012