Returning Clinical Trial Materials and Investigational Medicinal Products to the Trial Sponsor

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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	Date:	14th May 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	22nd March 2010	Pharmacy SOP put into revised template. Cross referenced forms and SOPs updated
3.0	2nd July 2012	Change of SOP Controller. Removal of references to the North and East Yorkshire Alliance. Major update to SOP and addition of returns tracking form.
4.0	22nd November 2013	Removal of references to Pharmacy Stores.
5.0	15th June 2015	Updated SOP to reference revision of returning clinical trial materials and IMP form Pharm/F83

Contents

1 Introduction, Background and Purpose

All Investigational Medicinal Products (IMPs) must be accounted for, all returned, expired, and any unused IMP's that are no longer required are either sent for destruction by the clinical trials team or returned to the Sponsor/Manufacturer. This SOP details the correct procedure to be followed when IMPs are returned to the sponsor.

This SOP also provides advice on how to document an audit trail for the return of IMPs and ensures that the Pharmacy Clinical Trials team are aware of IMPs that are awaiting collection by a courier.

2 Who Should Use This SOP

This procedure should be followed by all staff who handles IMP's within the Pharmacy Departments, within York Teaching Hospitals NHS Foundation Trust. This includes members of the Pharmacy Stores team who will be responsible for contacting the Pharmacy Clinical Trials team when a courier arrives to collect the return where applicable.

3 When this SOP Should be Used

This procedure must be followed by all members of the Pharmacy Clinical Trials team when returning IMP's to a Wholesaler, Manufacturer or Sponsor at the request of the sponsor.

4 Procedure(s)

1. The Sponsor/Pharmacy Clinical Trials team should ensure that all relevant accountability logs have been completed to accurately reflect the details of the IMP return. This may include checking completion of Sponsor provided accountability logs and accountability logs created at site.

2. The sponsor/Pharmacy Clinical Trials team should ensure that all patient name(s) on the IMP packaging are unreadable by crossing through them with a black marker pen.

3. Returns documentation should be packed according to instructions provided by the sponsor. This may involve placing copies of the returns documents inside each box or sealed in a plastic wallet and secured onto the outside of the box.

4. A copy should be taken of all documentation provided by the sponsor regarding the return. Any communication between the Pharmacy Clinical

Trials team and the sponsor or courier should also be documented. These should then be filed in the relevant section of the Pharmacy trial file.

5. All IMPs to be returned to the Sponsor/Manufacturer will be packaged by a member of the Pharmacy Clinical Trials team or the sponsor in an addressed and sealed cardboard box. The name of the courier collecting the IMPs should be written on the outside of the box. The destination address of the return should also be clearly visible to ensure it can be easily identified when the courier arrives to collect the parcel.

The sponsor should arrange a courier to collect the returned IMP, and an air waybill should be provided when necessary. If the sponsor is unable to arrange for a courier to collect returned IMP arrangements shall be agreed by pharmacy and the sponsor. Details regarding the collection should be obtained if possible. Courier collections from York Hospital Pharmacy Stores should be arranged for Monday to Friday between the hours of 09:00 and 17:00, Scarborough Hospital Pharmacy Stores should be arranged for Monday to Friday between the hours of 08:00 and 16:30.

A member of the Clinical Trials team should complete Pharm/F83 (Returning Clinical Trial Materials and Investigational Medicinal Products to the Trial Sponsor) with the following information:

Name of the clinical trial and protocol number (if applicable)
Destination address of the parcel
Name of the courier company who will be collecting the parcel Number of the air waybill (if one has been provided by the CRA).

a. Expected date of the courier collection.
b. Actual date and time of collection.
c. Name and signature of courier driver.
d. Signature of pharmacy clinical trials team member.

The box will be placed in Pharmacy Clinical Trials Dispensary/room in the area marked ‘Clinical Trial Returns to Sponsor’. A member of the Pharmacy Clinical Trials team will inform Pharmacy Stores that a courier is expected to collect a parcel from the Clinical Trials Team, informing them of expected date of collection if known.

8. When the courier arrives to collect the parcel, the Pharmacy Stores team will contact the Pharmacy Clinical Trials team to inform them that the courier has arrived. The Pharmacy Clinical Trials team will then take the parcel to Pharmacy Stores, and leave it with the courier, ensuring the courier signs and dates Pharm/F83. Any additional documentation should be completed as requested by the driver.

9. Pharm/F83 should be updated against the corresponding entry to confirm the date the parcel was given to the courier. The form should also be completed by the person who gave the parcel to the courier, ensuring all boxes are completed.

11. Copies of any documentation given to Pharmacy Clinical Trials team by the courier should be filed in the Pharmacy Study-specific Trial File.

5 Related SOPs and Documents

Pharm/S57	Destruction of Investigational Medicinal Product
Pharm/S56	Trial Closedown in Pharmacy
Pharm/F83	Returning Clinical Trial Materials and Investigational Medicinal Products to the Trial Sponsor
Pharm/T25	Pharmacy Trial Instructions