York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S55

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S55
Version Number:	7.0
Author:	Cheryl Donne
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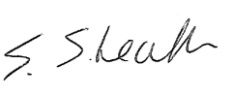
Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Signature:	
	Date:	7th June 2022
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	6th July 2022

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	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
6.0	4th March 2019	Review and SOP update. Discontinue IMP form Pharm/F38. Change of Author. Change of reviewer. Change of link to R&D website
7.0	27th July 2022	Minor updates

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.

2 Who Should Use This SOP

This procedure should be followed by all staff who handle IMP's within the Pharmacy Departments, within York and Scarborough 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. This will depend on the individual study requirements. The Monitor for the study may be needed to sign off and prepare the returns and sign off all the accountability logs for the stock being returned.

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 permanent marker pen or all additional patient identifying labels are removed.

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. The exact requirements will be study specific and will be documented in the Pharmacy trial instructions for individual studies or from the specific trial monitors.

4. A copy of all documentation provided by the sponsor regarding the return should be kept with any communication between the Pharmacy Clinical Trials team and the sponsor/courier should also be kept. 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. A suitable cardboard box should be acquired and prepared in line with the specific trial requirements. The expected courier and documentation required will be confirmed by the clinical trials team member assisting the sponsor/dealing with the return. They will then prepare the paperwork and package for the return collection.

6. All clinical trials personnel should be made aware of the pending collection and the means by which this is due, the location of the package and ant relevant documentation

The sponsor should arrange a courier to collect the returned IMP, and an air waybill should be provided when necessary. This may require a member of the clinical trials team to confirm arrangements online to finalise collection arrangements in line with sponsors directions, in this case copies of any documents should also be kept and filed in the Pharmacy site file.

Courier collections from York Hospital Pharmacy Stores should be arranged for Monday to Friday between the hours of 09:00 and 17:00.

The box will be placed in Pharmacy Clinical Trials Dispensary awaiting pick up or in the pharmacy stores department depending on the arrangements with the courier. 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/ collection from the stores area, informing them of expected date of collection if known.

7. 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 any additional documentation should be completed as requested by the driver.

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