York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S47

Storage of Clinical Trials Materials and Investigational Medicinal Products

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	22nd December 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	1st January 2010	
2.0	2nd July 2012	Storage of non-IMPs, storage of IMPs outside of Pharmacy, and locations of temperature monitoring. Removal of North and East Yorkshire R&D Alliance references. Change of SOP Controller.
3.0	24th October 2013	Incorporated Scarborough Hospital as a site working to this SOP. Removed out of date references to storage areas within Pharmacy at York. Added references to new SOP – Pharm/S76 – Storage and Dispensing the IMP outside Pharmacy.
4.0	19th January 2016	Small amendments to the SOP changing reference to York R&D Unit rather than R&D Manager, removing reference to Pharm/T25 as it will imminently be replaced and clarifying location of quarantine area in Pharmacy cold room.

Contents

1 Introduction, Background and Purpose

Clinical Trial materials and Investigational Medicinal Products (IMP) must be stored in accordance with current Clinical Trials legislation (The Clinical Trials Directive 2001/20/EC transposed into UK law through The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004 No.1031), Good Clinical Practice (GCP) and the Trust's Medicines Code. This requires storage arrangements and clear accountability records to ensure:

- adherence to any requirements set out in the protocol for the clinical trial
- adherence to the requirements of the Investigator's Brochure or Summary of Product Characteristics
- products are not supplied after their expiry date
- the quality of products has not been compromised prior to their expiry

The purpose of this SOP is to specify a suitable storage area for clinical trial stock, whilst ensuring all IMPs are separated from normal hospital stock.

2 Who Should Use This SOP

This procedure should be followed by all staff who handle clinical trial materials and IMP within the Pharmacy Department at York and Scarborough Hospital, which form part of York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used whenever Clinical Trial materials and IMP are being stored within York Teaching Hospital NHS Foundation Trust.

4 Procedure(s)

IMP must be stored in a secure area not accessible to unauthorised persons.

This area should be temperature monitored (See Pharm/S48) and all IMP should be segregated from normal hospital stock and clearly marked.

The IMP for each clinical trial should be individually segregated and stored with the relevant Pharmacy trial file if possible (depending on the size and location of the IMP stock).

4.1 Storage of Investigational Medicinal Products within Pharmacy

1. During the process of Pharmacy Assessment (see Pharm/S41) the required storage conditions for the IMP should be ascertained by reference to:
   - The Investigator's Brochure or Summary of Product Characteristics
   - The Protocol or Pharmacy Manual provided by the Sponsor

If there is any doubt as to how the product should be stored contact the Sponsor

2. During the process of completing the Pharmacy Trial Instructions the storage conditions of the IMP should be documented.

3. An area for the IMP to be stored in Pharmacy should be allocated as part of the trial set up process and noted in the Pharmacy clinical trial file and Pharmacy Trial Instructions. The allocation should be made in accordance with the required storage conditions and the areas available for storage as detailed below:

   - Room temperature storage (15ºC to 25ºC)
     - In York and Scarborough, IMP will be stored in the Clinical Trials Dispensary.
   - Refrigerated storage (2ºC to 8ºC)
     - In York, IMP will be stored in the Clinical Trials Refrigerators CTF1 and CTF2 in the Clinical Trials Dispensary and the main Pharmacy Cold room.
     - In Scarborough, IMP will be stored in the Clinical Trial Refrigerators in the Clinical Trials Dispensary.
   - Frozen storage – arrangements should be discussed with the trial Sponsor when considering the Pharmacy Assessment (Pharm/S41). It may be possible to request a freezer from the Sponsor.

4. There are also quarantine storage areas for IMP/Clinical Trials materials in the Clinical Trials Dispensary in York and Scarborough. In York, a clearly marked area of the Pharmacy cold room (2ºC to 8ºC) and a marked bay of the Clinical Trials shelving (15ºC to 25ºC) are in use. In Scarborough, there are clearly marked quarantine storage areas within the Clinical Trials Dispensary and the refrigerators within. These should be used to store IMP if the product has expired, is awaiting QP certificate of release, or has been subject to a temperature excursion. Quarantine documentation should be completed when IMP is stored in these areas. The procedure for this is detailed in Pharm/S59.

5. Any supplies returned by the patient or Research Nurse after use must be stored in the Clinical Trials Dispensary in the box labelled ‘Clinical Trials Returns’. Once they have been reconciled and logged in the relevant Pharmacy clinical trial file, they will be stored in the bay (or cupboard in Scarborough) marked ‘returns’ in the Clinical Trials Dispensary, separated from normal hospital stock and undispensed/unused IMP.

6. A record of storage temperature conditions should be maintained for each of the locations where current supplies of IMP are stored (see section 3 and 4 above). If the Sponsor provides a specific form for recording the storage conditions for the trial, ask if we can use our standard computer printout generated by the monitoring arrangements described below. Temperature monitoring arrangements will be described during the production of the Pharmacy Trial Instructions.

7. Temperatures will be monitored electronically using a validated temperature monitoring system or device for recording ambient and refrigerated conditions (and frozen storage conditions if applicable).

   Temperatures of the IMP storage areas within Pharmacy are also recorded manually each working day (Monday to Friday, except Bank Holidays).

   The process for doing this can be found in Pharm/S48 (Temperature monitoring).

8. Any study specific SOPs regarding specific storage instructions should be adhered to. This may involve storing IMPs under frozen conditions, or storing IMPs outside of the Pharmacy department (see section 4.3 also). The responsibilities of the research team and Pharmacy clinical trials team should be defined and understood by all those involved in these circumstances and these should be documented in a study specific SOP (see Preparation, Review and Approval of Standard Operating Procedures for Research (R&D/S26)). If IMP stored outside Pharmacy is going to be dispensed by persons other than the Pharmacy clinical trials team, this study specific SOP should document the dispensing process they are going to follow. In addition, training of relevant research team members (in the study specific SOP) should be documented using Pharm/F61 – Pharmacy training record. See Pharm/S76 – Storage and Dispensing the IMP outside of Pharmacy for more detailed guidance on this subject.

4.2 Storage of non-Investigational Medicinal Products within Pharmacy

Non-IMPs should be stored following the same procedures for IMPs; therefore the product will be stored in a secure area not accessible to unauthorised persons. This area should also be temperature monitored and products will usually be segregated from normal hospital stock and clearly marked for this purpose. Trial-specific SOPs created by the Sponsor should also be followed when provided (see the Pharmacy Trial Instructions for each individual trial).

4.3 Storage of Investigational Medicinal Products outside Pharmacy

It is acceptable for the IMP to be managed by the Investigator. For example, in some trials it may be necessary to store clinical trial supplies or IMP on the ward or another location in the Trust where they can be accessed in an emergency by the Principal Investigator or Research Nurse responsible. Clinical trial supplies or IMP may also need to be stored outside of the Pharmacy if a patient is attending a clinic appointment that will require medication and this occurs outside the normal opening hours of the Pharmacy (8.45 am to 5.15 pm). There may also be other circumstances where Pharmacy cannot provide the service in relation to the trial (e.g. patient attendance at an off-site unit e.g. GUM Clinic) however this can be provided by the Principal Investigator/Research Team.

If this is necessary, each storage area will need to be assessed by the Pharmacy clinical trials team to ensure that it is safe, secure and has the correct environmental conditions for the relevant IMP (and can be temperature monitored) before it is agreed that the supplies can be stored in this location. A Room Assessment form (Pharm/F89) should be used for this

purpose. Arrangements must be made and documented regarding a secure system of drug accountability, expiry date checks and for appropriate storage records to be maintained as well as clearly defined roles and documentation regarding prescribing and dispensing of the IMP.

Procedures will need to be documented within the Pharmacy Trial Instructions to ensure that supplies stored outside the Pharmacy department are stored and accounted for as indicated in the protocol.

In addition to this, as mentioned in section 4.1 (part 8), in all cases where IMP is being stored outside Pharmacy and elements of the IMP control process are being shared by Pharmacy staff and other staff (for example Research Nurses), the arrangements made must be documented in a Study-Specific Standard Operating Procedure in accordance with R&D/S26. The Study-Specific SOP must be authorised by the clinical trials Pharmacist and Principal Investigator for the trial, and a copy sent to the York R&D Unit. Pharm/S76 describes the procedures for documenting these arrangements.

5 Related SOPs and Documents

PHARM/S59	Quarantine of IMP (Clinical Trials)
PHARM/S55	Returning Clinical Trials materials and IMP
PHARM/S48	Temperature Monitoring (Clinical Trials)
PHARM/S41	Pharmacy Trial Assessment and Confirmation of Readiness
PHARM/F61	Pharmacy training record
R&D/S26	Preparation, review and approval of Standard Operating Procedures for Research
Pharm/S76	Storage and Dispensing of Investigational Medicinal Products outside of Pharmacy
Pharm/F89	Assessing an area for Investigational Medicinal Product storage outside of Pharmacy