York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S59

Quarantine of Investigational Medicinal Product (IMP)

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	3rd June 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	23rd April 2009	
2.0	1st January 2010	Pharmacy SOP put into revised template. Cross referenced forms and SOPs updated
3.0	16th May 2013	Change of SOP Controller. Inclusion of Scarborough as a site using this SOP. Minor alterations/clarification of the process.
4.0	1st July 2015	Minor changes only

Contents

1 Introduction, Background and Purpose

This SOP describes the procedure for quarantine of clinical trial material or Investigational Medicinal Product (IMP) for any reason (e.g. unfit for purpose, subject to a temperature excursion, expired, drug recall etc) to prevent further use of the IMP. Quarantine may be temporarily or permanently imposed depending on the circumstances, and it is important to maintain an audit trail for all IMP being placed into, and being subsequently removed from, quarantine.

If it is not clear that an IMP is in quarantine there is a risk that it will be dispensed to patients and therefore, the procedures described within are there to safeguard clinical trial patients.
This SOP is written to ensure compliance with Good Manufacturing Practice (GMP), the UK Clinical Trials Regulations and the Medicines Act 1968.

2 Who Should Use This SOP

This SOP applies to the Pharmacy Clinical Trials teams within York and Scarborough Hospitals (which form part of the York Teaching Hospital NHS Foundation Trust) and all pharmacy staff involved in the storage of Investigational Medicinal Products (IMPs). It is also applicable to Research Nurses, Clinical Trials Assistants and other members of Research Teams in circumstances where IMP is stored outside Pharmacy.

3 When this SOP Should be Used

This procedure relates to the quarantine of all IMPs considered to be unfit for purpose or use. This may be due to one of the following reasons (although there may be other reasons for quarantining also);

- Product recall.
- Storage temperature deviation.
- Product expiry.
- End of study.
- Request of a Clinical Research Associate.

4 Procedure(s)

If an IMP is unfit for purpose, for one of the reasons detailed above, it should be placed into quarantine so it cannot be dispensed to a patient. If quarantine is required as a result of a drug recall, please also refer to Pharm/S58. If quarantine is required as a result of a temperature excursion, please also refer to Pharm/S48.
The study specific quarantine procedures that should be followed by Research Nurses, Clinical Trial Assistants and other members of the Research Team, in circumstances where IMP is stored outside Pharmacy, will be described in a study specific SOP (See Pharm/S76). This SOP will refer to the processes and associated forms described below.

4.1 Placing an IMP into quarantine

1. Place the IMP in a sealable container or bag and complete the 'quarantine imposed' section of the Quarantine Notice (Pharm/F42). Place this form together with the IMP in the sealable container, in such a way that it is clearly visible that the IMP within is in quarantine.

2. Store the quarantined IMP according to its storage requirements, in the clearly marked quarantine area.

   Clearly marked, quarantine storage areas are available in York and Scarborough Hospitals. If for any reason there is no available space for the IMP in quarantine, seek advice from the Clinical Trials Manager, Pharmacist or Senior Pharmacy Technician.

3. Complete the Quarantine log (Pharm/F43). A separate log is in place for each quarantine storage location. Ensure that the entry made onto the log is specific enough to enable identification of the exact quantities of IMP that were placed into quarantine and their respective batch numbers and expiry dates. This is to ensure an accurate audit trail for the process can be evidenced.

4.2 Release from Quarantine Procedure

1. When written confirmation has been received that the IMP is still fit for use, or is to be returned to the sponsor (or authorisation has been received to destroy it locally), the IMP can be removed from quarantine and dealt with according to the Sponsors instructions.

2. Complete the Quarantine log (Pharm/F43) with date of removal, action taken and your signature.

3. Complete the Quarantine Notice (Pharm/F42), which is stored with the IMP, stating why the material can be removed from quarantine in the outcome section, and print, sign and date the form.

4. File the Quarantine Notice (Pharm/F42) in the pharmacy clinical trial file. This may be required to be sent to a Sponsor as evidence that quarantine has been imposed.

5. If IMP is to be used after quarantine, return it to its designated clinical trial location. If IMP is NOT to be reused, process it in line with the Sponsors' instructions.

5 Related SOPs and Documents

Pharm/S58	Recall of IMP
Pharm/F42	Quarantine Notice
Pharm/F43	Quarantine Log
The Medicines Act	1968

Good Manufacturing Practice Current version
Good Clinical Practice Guide 2012 (the grey guide)