York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S59

Quarantine of Investigational Medicinal Product (IMP)

IT IS THE RESPONSIBILITY OF <u>ALL</u> 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Daniel Hobson
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	10th September 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	9th September 2024

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	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
5.0	6th March 2019		Change of link to R&D website. Change of author and reviewed section added to accommodate for sending IMP to Scarborough site.
6.0	9th December 2019		Change of author. Language changed in 4.1 to reflect amended filing and storage of Quarantine paperwork.
7.0	2nd November 2020		Change of author. Details about adding a note to the master accountability log when stock is in quarantine.
8.0	7th October 2024	Rachel Spooner	Change of author. No changes required.

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 all members of the Pharmacy Clinical Trials teams. 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.
- Damaged or defected product

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, or a temperature excursion, please also refer to the relevant corresponding SOP's.

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. This SOP will refer to the processes and associated forms described below.

If IMP has been sent on transport between the York and Scarborough sites and has encountered damage or a temperature excursion during transit. The member

of staff receiving will inform the pharmacy clinical trials team and they will be instructed to send the affected stock back to York to be quarantined. This is outlined in the study pharmacy specific SOP.

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). Firmly attach this form to the front of the sealable container/ bag containing the IMP, in such a way that the information on the notice 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. For ambient storage requirements place in the lockable storage cabinet labelled quarantined stock in the clinical trials dispensary. For refrigerated storage requirements place in the designated signed area of a clinical trials fridge or the cold room.

   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 relevant Quarantine log (Pharm/F43) for the IMP temperature requirements. All logs are located in the master quarantine folder in the lockable storage cabinet in the clinical trials dispensary. 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. Ensure that when stock is put into quarantine that a note is placed into the PSF with the Master Accountability Log to indicate that some of the stock is held in the quarantine area. This allows stock to be easily allocated.

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 by destroying or returning it back to the sponsor by following the relevant SOPs to perform these tasks.

5   Related SOPs and Documents

Pharm/S58	Actioning a Clinical Trial Investigational Medicinal Product Recall
Pharm/F42	Quarantine Notice
Pharm/F43	Quarantine Log