Royal Papworth Hospital
NHS Foundation Trust

Document Title: Quarantine of IMP's (Investigational Medicinal Products)

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Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Summary of Amendments

Version Number	Modification:
3.0	Minor changes throughout
4.0	Minor changes and clarifications

Key related documents:	FRM035 CTIMP under quarantine FRM036 CTIMP Quarantine File Log CT23 Temperature Monitoring and Maintenance of Clinical Trial Storage Areas SOP074 Handling of medicine recalls of Investigational Medicinal Products (IMPs) or other trial related drugs

Key Points of this Document

- To describe the process for placing an Investigational Medicinal Product (IMP) in quarantine and processing the necessary documentation.

1 Purpose and Contents

a. This document defines the procedure for placing clinical trial investigational material (IMP) under quarantine and the circumstances in which quarantine is required.

b. This SOP does not cover NIMPs, as these are managed under the relevant general medicine regulations

c. This document contains the steps to follow when placing an IMP under quarantine and the process for returning an IMP back into clinical trial supply.

d. An IMP may be required to be quarantined for a number of reasons such as:

1. Product stored outside of recommended temperature requirements
2. Documentation to prove suitability of IMP not available
3. A drug recall
4. Product expiry
5. Damaged or defected IMP
6. IMP has been received by pharmacy ahead of final Trust approval and pharmacy green light

e. Whenever there is any concern as to the suitability of the IMP for use in humans it must be quarantined until further advice has been given from the manufacturer or sponsor overseeing the trial.

f. If quarantine is required as a result of a drug recall or temperature excursion, also refer to the relevant corresponding SOPs (see section 4.1).

2 Roles & Responsibilities

a. This document applies to all areas where IMPs are stored.

b. All members of staff undertaking research involving an IMP should be aware of this document and the processes required.

c. It is the Investigator's responsibility to ensure that adequate processes are in place to protect subjects from receiving unsuitable IMP during a clinical trial – aspects of this role may be delegated to pharmacy or other members of the research team with IMP handling responsibilities.

d. The SOP committee is responsible for reviewing this SOP and for monitoring adherence to this SOP.

3 Policy

a. All research staff should be aware of this SOP at the commencement of the research project. Failure to follow this SOP may result in disciplinary procedures.

4 Procedure

4.1 Placing IMP into quarantine

a. A request to quarantine may come from a number of sources including:

1. A drug recall by the manufacturer/Sponsor/MHRA (Also refer to SOP074: Handling of medicine recalls of Investigational Medicinal Products (IMPs) or other trial related drugs)
2. The clinical trials pharmacy team – on the reporting of a storage or transport temperature deviation (See CT23 Temperature Monitoring and Maintenance of Clinical Trial Storage Areas as well)
3. The investigator or delegate – on noticing a problem with the IMP

b. On the receipt of a request to quarantine, the staff responsible for IMP management should respond immediately and no later than the start of the next working day.

c. Complete the form – IMP under Quarantine (FRM035) with the information provided including:

1. Name of IMP
2. Protocol
3. Batch numbers of affected batches
4. Reason for quarantine
5. Action required

d. All IMPs placed under quarantine should be returned to the Clinical Trials Pharmacy Department unless it is specified otherwise in the trial specific IMP Handling Guidelines.

e. Remove all affected batches of IMP from the dedicated storage area and place in a suitable, clearly marked quarantine location. If the IMP needs to be stored in a fridge or freezer, place the IMP on the lower shelf/basket of the fridge or freezer and mark the shelf with a QUARANTINE label.

f. If possible, place the items in a clear plastic bag and place a quarantine label on the bag. If the item is too large place the quarantine sticker on the box itself. The label text should read:

IMP Under Quarantine – DO NOT USE
See quarantine folder for further information

g. Place the completed quarantine form (FRM035) in the Quarantine File.

h. Fill in the quarantine log (FRM036) in the front of the Quarantine File.

i. Inform the sponsor, Investigator and manufacturer (if applicable) of the affected stock. Mark the affected items 'in quarantine' in the sponsor Interactive Response Technology (IRT) system if instructed to do so.

4.2 Release from quarantine procedure

a. Authorisation for releasing IMP from quarantine must be provided, in writing (email is acceptable), from the trial sponsor. For Royal Papworth sponsored/managed trials this must be one of the following: Clinical director of R&D (or their deputy); Senior R&D Manager or the Clinical Project Manager responsible for the trial concerned. This authorisation must be printed and filed alongside the quarantine form as detailed below.

b. If the product does not meet specification, then it should be returned to the manufacturer for investigation – in this case it would be usual for the manufacturer/sponsor to resupply the IMP.

c. If the product is not authorised for re-use attach copy of communication to the quarantine form (FRM035), place product in appropriate returns bin (do not remove from quarantine bag or take off quarantine stickers) and amend drug accountability logs to reflect active stock numbers.

d. If appropriate, once authorisation has been given to reuse the product attach a printout of the email or the letter to the quarantine form (FRM035) and document on the form the date authorisation to re-use was received. Ensure batch numbers authorised match the batch numbers in the quarantine area.

e. Remove the authorised batches and place it back in the designated storage location.

f. File quarantine note and authorisation in trial specific Pharmacy Site File under Correspondence.

g. Update the quarantine log (FRM036) in the Quarantine File to reflect current quarantine list.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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Yes/No	No	No	No	No	No	No	No

Positive/Negative							
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