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

Document Number: PTUC SOP075

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
3.0	**Minor changes throughout**

Key Points of this Document

- To describe the process for placing an 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 document contains the steps to follow when placing a IMP under quarantine and the process for returning a IMP back into clinical trial supply.

c. 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. Manufacturer instigates a drug recall
4. IMP has been received by pharmacy ahead of final trust approval and pharmacy green light

d. 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.

2 Roles & Responsibilities

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

b. All members of staff undertaking research involving a 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

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

1. The manufacturer – as a drug recall
2. The clinical trials pharmacy team – on the reporting of a storage or transport temperature deviation
3. The investigator or delegate – on noticing a problem with the product

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 (if stored at a location away from this).

e. Remove all affected batches of IMP from the shelf/draw location and place on the quarantine shelf/draw. The quarantine area should be clearly labelled with the words QUARANTINE. If the item needs to be stored in a fridge or freezer place the items on the lower shelf/basket of the fridge or freezer and label the shelf with QUARANTINE..

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 on the quarantine shelf.

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

i. Inform the sponsor, investigator and manufacturer of the affected stock. Mark the affected items 'in quarantine' in the sponsor Interactive Response Technology (IRT) system if instructed to do so. Discuss with the sponsor/manufacturer if a temperature deviation has occurred to confirm suitability for re-use or reduced expiry etc.

j. 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/deputy director of R&D; 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.

k. 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.

l. 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.

m. If appropriate, once authorisation has been given to reuse the product attach a print out 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 on the quarantine shelf.

n. Remove the authorised batches and place on appropriate shelf in the clinical trials room.

o. File quarantine note and authorisation in trial specific Pharmacy file under Correspondence

p. Complete quarantine log (FRM036) in 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 (2018)
Key related documents:	Trust Research Policy FRM035 CTIMP under quarantine FRM036 Quarantine File Log

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative							

Review date:	February 2023

I certify the contents of this SOP has been reviewed and ratified

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Signed by Dr Ian Smith, Clinical Director of R&D

20th February 2020

Date

SOP release date: 4th March 2020