Royal Papworth Hospital
NHS Foundation Trust

Document Title: SOPs: Returns of IMP to Pharmacy

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Summary of Amendments

Version Number	Modification:
2.0	**Clarification regarding handling of returns and other minor changes**
1.0	New SOP

Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures SOP072 Supply of Clinical Trials Investigational Material: Dispensing, Returns and Accountability FRM074 Form Returns Slip for IMP Returns

Key Points of this Document

- It is often a stipulation of the trial protocol that investigational medicinal product (IMP) returns (unused and used medicines and packaging) are collected by pharmacy and accounted for until verification by the Sponsor's monitor can be completed.
- It is not appropriate that unused medicines be returned to local pharmacies unless specifically described in the study protocol or sponsor's Pharmacy Manual.
- Pharmacy staff and research staff need to be aware of the safe processes for handing returns of IMP and packaging from patient's homes and from ward areas.

1. Purpose and Content

a. To ensure that IMP returns (used packaging and unused IMP) are returned to pharmacy in a safe manner, not exposing pharmacy staff to risk of infection or risk of exposure to hazardous substances or harmful packaging including sharps waste.

b. To ensure IMP returns are acknowledged by pharmacy and stored appropriately so that they may be accounted for at all times until monitor verification can occur.

c. This procedure details how returns of IMP should be managed by those handing the returned items to pharmacy and by pharmacy staff processing those returns.

2. Roles and Responsibilities

a. Pharmacy is delegated the responsibility for IMP management and accountability within a clinical trial.

b. The pharmacist for clinical trials is responsible for ensuring staff handling returned IMP are not put under unnecessary risk.

c. Any staff member who works with clinical trials must be aware of and adhere to this procedure.

3. Policy

a. All Pharmacy staff members are to read and be aware of this procedure as part of their induction.

b. Where the protocol does not require the IMP to be returned for accountability the subject should be given clear advice on how to dispose of unused IMP in the community i.e. taken to a local pharmacy. NB if the quantity of IMP to be returned is significant then it may be reasonable to suggest returns are made to the hospital to avoid undue burden on small community pharmacies.

c. Pharmacy clinical trials will not accept returns that include any of the below:

1. Cytotoxic medicines (must be disposed of at ward level) – packaging only accepted.

   - Oral cytotoxic medicines such as methotrexate may be returned if in original sealed packs such as blister packs.

2. Sharps waste including needles and broken glass.

3. Medical devices (to be returned to study team).

4. Unsealed containers containing IMP i.e. open sachets, ampoules, loose tablets or capsules.

5. Medicines that are not part of a clinical trial or not part of a trial run by Royal Papworth Hospital NHS Foundation Trust.

   - Drugs prescribed for another trial not run by Royal Papworth should be returned to the original prescribing centre.

   - Drugs that are not part of a clinical trial should be returned to a local pharmacy for destruction.

4. Procedure for pharmacy staff

4.1 Acceptance of clinical trial returns from patient's homes

1. IMP for clinical trials is returned to pharmacy via the clinical research team staff usually over the hatch or in person to the pharmacy trials staff.

2. IMP returns may also be sent via courier directly back to the pharmacy (from patients' homes) if agreed by trial Sponsor.

3. Trial returns should comply with the above criteria i.e. no cytotoxics, no sharps, no loose medication, and be part of a study conducted by Royal Papworth Hospital NHS Foundation Trust.

4. Confirm with the research staff member bringing the returns:

    - The study / protocol;
    - Subject number;
    - The date the returns were brought back to the hospital;
    - Ensure a completed returns slip is attached (FRM074)

5. Returns should be brought back in a single container / bag where possible to avoid them becoming separated. **Do not touch face whilst handling patient returns and wash hands following handling.**

6. Any loose tablets or capsules should be placed immediately into a sealable plastic bag (available from pharmacy) if possible and labelled with subject number, protocol and visit date.

7. Place the returns in the grey 'RETURNS for processing' box NB if the IMP is classed as a controlled drug (CD) then the returns should be bagged and placed in the CD cupboard - clearly labelled and entered into the relevant CD register. If it is not possible to clearly describe the quantity of CD returned, then enter into the register as '1 box' for example and then re-enter actual quantities when the returns have been counted safely.

8. **It is not always necessary to wear gloves when handling returns for accountability (e.g. sealed packaging), but hands must be washed when the process is complete and surfaces / tray / counting triangles wiped**.

9. **If there is evidence of spillage or the risks of the product require the wearing of PPE (e.g. gloves and/or a mask) according to the Pharmacy risk assessment, then these should be used as required and disposed of once the process has been completed.**

10. Once accountability is complete, obscure the patient's name on the label, re-bag the returns and place in the relevant black tote labelled for the study until the monitor can verify/ authorise return to Sponsor for destruction as agreed.

2. **Where a subject is unable to bring returns back to the hospital**

    1. If it is not safe for the subject to bring their returns back to the hospital or if it is unsafe for returns to be accepted, then the subject should be advised:

        - **Not** to dispose of medicines via normal household rubbish or pour down the drain;
        - To store the medicines securely in a labelled and sealed box/bag;

- To keep medicines out of reach of children and vulnerable individuals and away from other medicines that are in use;
- To consider placing in a garage or attic but not near heat sources or running water.

2. This is until such time when it does become safe to bring the medicines back to the hospital.

3. **Advice for research staff handling patient IMP returns:**

1. Try to handle the IMP in a clear and defined space that can be easily wiped down. If the IMP is outside of the sealed packaging, do not handle the returns directly- always wear appropriate PPE (e.g. gloves, mask) as specified in the Pharmacy Risk Assessment. They should be removed once the process is completed.

2. Do not touch face during / after handling the IMP.

3. Wash hands immediately after the process and wipe down any surfaces and equipment used.

4. Where there is more than one container, if possible, bag the returns together before binging to pharmacy to prevent them from becoming separated.

5. Study Team staff should not count or check the IMP immediately for accountability/compliance. Pharmacy will inform the study team of return quantities.

6. Complete the returns slip (FRM074) prior to returning the IMP to pharmacy.

7. Do not hold returned IMP in pockets or on desks – it should be returned as soon as possible to pharmacy, on the same day as the patient visit.

8. Returns will be stored until the next on-site monitoring visit when they will be verified and then removed for destruction or return to sponsor.

4. **Acceptance of clinical trial returns from ward areas:**

1. Where study IMP is administered to inpatients as part of a study clear instructions regarding returns should be given to staff undertaking this process (research or ward staff).

2. Where returns to pharmacy are required, pharmacy will not accept prohibited items (see section 3.c).

3. Allowable returns or packaging should be returned once no longer required on the ward.

4. Upon return pharmacy will place the bag into the grey ‘RETURNS for processing’ box until they can be processed.

5. **In case of pandemic:**

    1. No IMP returns from outpatients should be made in person to the hospital during times where the Government has placed restrictions on unnecessary travel. If mandated by Sponsor, then a courier service can be used.

    2. Where a subject is unwell with symptoms related to the pandemic or is living with someone who has symptoms then **no IMP returns should be made at this time via courier or otherwise**. Returns should only be made when the entire household comes out of quarantine.

    3. **For inpatient returns:** If the returns are coming back from a ward area where there are known cases of infectious disease being treated (i.e. staff are wearing full PPE in that area) then the IMP should be placed in a plastic bag which must be completely wiped down with a Clinell wipe before bringing back to pharmacy. Upon return pharmacy will place the bag into the grey 'returns for processing' box and leave for a minimum of 5 days before handling.

    4. **For inpatient returns from green areas (i.e. no precautions required) then IMP can be returned to pharmacy as usual.**

5. Risk Management/Liability/Monitoring and Audit

1. The Senior Specialist Pharmacist for Clinical Trials and R&D SOP Committee will ensure that this SOP and any future changes are adequately disseminated.

2. The Senior Specialist Pharmacist for Clinical Trials and the R&D Department will monitor adherence to this SOP via departmental oversight and via routine monitoring of individual clinical trials respectively.

3. In exceptional circumstances it may be necessary to deviate from this SOP for which written approval from the Senior R&D Manager and if necessary, the relevant trial sponsors should be gained. Any deviations (planned or otherwise) should be recorded including details of alternative procedures followed and filed in the Pharmacy File and Site File.

4. The Chief Pharmacist and Research and Development Directorate are responsible for the approval of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version 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 (2023)

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

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