Royal Papworth Hospital
NHS Foundation Trust

Document Title: Destruction of Waste IMP (Investigational Medicinal Product)

Document Number: R&D SOP081

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	Modification:
All	To add clarifications throughout and update Appendix 1 with new form

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in research
- It provides clear guidance on the steps involved in the destruction of waste investigational medicinal products (IMP) to ensure compliance with the Trust's policies.

1 Purpose and Content

a. To describe the process for the removal or destruction of investigational medicinal products (IMPs) that is no longer required for trial purposes.

b. Unused trial medicines must usually be destroyed after study close down upon Sponsor's (or delegated representative) authorisation.

c. IMPs may require destruction for reason such as: partially used or unused IMPs being returned to Pharmacy for accountability; IMP expires; IMP is deemed unsuitable for use post quarantine, or the IMP was never dispensed to the subject.

2 Roles and Responsibilities

a. It is the responsibility of the Sponsor in conjunction with Pharmacy to determine the most appropriate means of drug disposal; this will be determined during study set up and detailed in a trial specific destruction procedure, which will be detailed in the Pharmacy Manual and IMP Handling Guidelines for the study.

b. It is the responsibility of the Sponsor and Pharmacy to ensure appropriate records of destruction are maintained.

c. It is the Sponsor's (or a delegated representative) responsibility to authorise IMP destruction.

d. Pharmacy shall be responsible for arranging and/or carrying out destruction according to the agreed procedure.

3 Policy

a. All Pharmacy staff and any other staff with direct responsibility for IMP should read and follow this policy in conjunction with other Pharmacy and R&D SOPs.

1. Royal Papworth Hospital NHS Foundation Trust does not have onsite facilities for drug destruction and so cannot provide onsite destruction or destruction certificates.

2. Where the IMP poses significant risks to staff, patients or other personnel and must be destroyed immediately (i.e. not stored for Sponsor collection) then it is possible for IMP to be sent for destruction by Royal Papworth Hospital NHS Foundation Trust.

4 Procedure

4.1 Commercially Sponsored Studies:

a. Except by prior agreement, all trial IMP from commercially sponsored studies must be removed from the Trust site Pharmacy by the Sponsor. Royal Papworth Hospital NHS Foundation Trust will not routinely destroy any IMP on behalf of external Sponsors.

4.2 Non-commercially Sponsored studies:

a. These may or may not require the IMP to be destroyed by site depending on the nature of the drug and how the IMP was obtained (i.e. IMP that is taken from routine Pharmacy stock may be returned to stock)

b. Where destruction is required, then following final IMP accountability by the Study Monitor and authorisation for destruction from the Sponsor, the normal drug destruction routes will be followed.

c. Where it is deemed that IMP destruction should be managed by Royal Papworth Hospital NHS Foundation Trust there will be an additional cost to the Sponsor to cover this service.

d. Royal Papworth Hospital NHS Foundation Trust does not have onsite facilities for drug destruction and so cannot provide onsite destruction or formal certificates of destruction.

e. If a formal certificate of destruction is required it is the Sponsor's responsibility to make arrangements to this effect directly with the waste company and inform the Pharmacy team of the process to follow. Where Royal Papworth is the Sponsor, the Trust Pharmacy will assist with these arrangements.

4.3 Hazardous Waste

a. IMP that is hazardous to health in any way must be packaged according to the materials data safety sheet (MSDS or COSHH) report and/or manufacturer instructions and disposed of in labelled bins and sealed immediately, see DN375 Appendix F.

b. A specific trial protocol should be written to cover the exact process which should be Sponsor approved.

c. If the IMP container needs to be disposed of or destroyed immediately after use then the outer packaging including labels should be retained for reconciliation (if required).

4.4 Royal Papworth Sponsored Studies

a. Where Royal Papworth Hospital NHS Foundation Trust is the Sponsor of the trial then the requirements for IMP destruction should be agreed prior to R&D approval of the trial.

b. An appropriate documentation trail should be maintained for the IMP, when it was authorised for destruction (by Sponsor) and when it was sent for destruction (by Pharmacy) using FRM081. (See Appendix 1)

c. Final IMP accountability needs to be approved at the final close out visit by the Study Monitor prior to Sponsor authorisation of IMP destruction.

d. IMP awaiting destruction should be stored in a separate container clearly labelled with the name of the trial and the words "For Destruction once authorised"

e. Once final accountability is signed off by the PI (as part of the final monitoring report) the destruction of the IMP must be authorised by either the Sponsor or the delegated representative.

f. The Sponsor should only authorise IMP destruction once the study database has been hard locked. This allows for the IMP to be re-reviewed if there is any discrepancy in the trial that may be related to the IMP. If storage of IMP waste is an issue due to lack of

space then earlier destruction may be able to be arranged post final monitoring and upon Sponsor (or a delegated representative) authorisation.

4.4.2 Process for destruction

a. Destruction of Clinical Trial material must comply with the relevant Trust policies and procedures.

b. In case of a pandemic, before the IMP can be placed in the relevant waste container, the Clinical Research team and Pharmacy staff must follow the procedure outlined in CT32: Safe Handling of Returned Investigational Medicinal Products.

5 Risk Management / Liability / Monitoring & Audit

a. 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).

b. 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 Trial Master File (in both the Site and Sponsor File).

Appendix 1: FRM081

Please refer to SOP081 for full procedure.

All IMP that is no longer suitable for use in a study may be destroyed upon the authorisation of the Sponsor (or a delegated representative) following verification of drug accountability as required by the study protocol.

IMP for commercial studies may be destroyed by Royal Papworth Hospital NHS Foundation Trust Pharmacy if it has been agreed and in the current study contract – however return to Sponsor is preferred. NB Certificates of destruction will not be provided

Details of Study

Study Name/Protocol #			
R&D No		PI	
Monitor		R&D study manager	
Site # (if multisite)		Pharmacist	
Sponsor		Sponsor approver (name)	

Authorisation checks

Description of IMP for destruction NB if multiple drugs per study then complete one form for each	i.e drug name, form, strength.
Reason for destruction:	
Decision agreed by/at meeting (date):	
Date of last monitoring visit:	
Any outstanding IMP related issues:	

Clinical Study Report complete: Accountability logs verified and up to date	**Yes☐ No ☐** **Yes☐ No ☐**
How will IMP be destroyed and by who?	

Description of IMP for destruction:

Type of IMP	**Tick**	**Details or attach IWRS report with full details**	**Quantity destroyed**
Patient returns		**Subject numbers (or all):**	
Unused Stock		**BN:** **Exp:**	
		BN: **Exp:**	
		BN: **Exp:**	
Expired Stock		**BN:** **Exp:**	
		BN: **Exp:**	
		BN: **Exp:**	
Damaged Stock		**BN:** **Exp:**	

Destruction Authorised by:

I authorise the destruction of all above described IMP for this study

Name:	
Role: (Sponsor Representative)	
Date:	

Pharmacy to complete:

All IMP described above has been verified by a monitor and there are no outstanding issues relating to the IMP for these subjects/ this trial.

The above documented returns have been placed for destruction in the relevant waste container and sealed as per the trust policy for the disposal of pharmaceutical waste. A certificate of destruction will not be issued.

Destroyed by		Signature		Date	
Witnessed by		Signature		Date	

File original in Pharmacy Site File, a copy should be sent to the trial CPM/Trials co-ordinator for evidence of action.

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 DN375 – Waste Management Policy DN212 – Procedure for the destruction of expired stock/redundant patients own controlled drugs CT32- Safe Handling of Returned Investigational Medicinal Products

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:	March 2025

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

DocuSigned by:
Dr Patrick Calvert
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Signed by Dr Patrick Calvert, Clinical Director of R&D

12-Mar-2022
Date