

Destruction of Investigational Medicinal Product

IT IS THE RESPONSIBILITY OF ALL 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 R&D Newsletter 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html

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Author:	Richard Evans
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Approved by:	Name/Position:	Jax Westmoreland, Principal Pharmacist, Clinical Trials and Research
	Signature:	Signed copy held by R&D Unit
	Date:	24 th June 2015
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	24 th June 2015

This SOP will normally be reviewed every 2 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	Details of significant changes
1.0	8 th November 2010	
2.0	17 th June 2013	Change of SOP Controller. Addition of Scarborough hospital as a site using this SOP. Minor alterations to the SOP.
3.0	27 th July 2015	Minor alterations to the SOP. Change of author.

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	2
4 Procedure(s)	2
4.1 Storage of IMP for disposal	2
4.2 Accountability checks and recording return of IMP to Pharmacy	2
4.3 Methods of destruction of IMP	3
4.3.1 Returning IMP to the Sponsor for Destruction	3
4.3.2 Destruction 'on site'	4
4.4 Destruction of IMP – Records	4
5 Related SOPs and Documents	Error! Bookmark not defined.

1 Introduction, Background and Purpose

Introduction:

All clinical trials materials and Investigational Medicinal Products (IMP) that have been used, partially used, or unused but are no longer required for the study, including expired clinical trials IMP, must be reconciled and disposed of appropriately, in accordance with current guidelines and legal requirements as follows:

- (i) Good Clinical Practice (GCP) requirements on supply and handling of Investigational Medicinal Product.
- (ii) RPSGB - Pharmaceutical Manufacture and Distribution.
- (iii) York Teaching Hospital NHS Foundation Trust - Medicines Code.
- (iv) York Teaching Hospital NHS Foundation Trust - Waste Management Policy.
- (v) Annex 13 Good Manufacturing Practice.

Background:

During and at the end of the clinical trial study, IMP returned by patients and all supplies of IMP not dispensed need to be returned to the Sponsor of the relevant clinical trial or destroyed at site. This must be done with approval from the Sponsor and must be fully documented.

Purpose:

The purpose of this SOP is to ensure that;

- Clinical trials materials and IMP no longer required for the clinical trial are accounted for, reconciled and disposed of according to the Sponsor and the Trust's requirements.
- IMP disposal is documented in the Pharmacy trial file in order to maintain an audit trail.
- All members of Pharmacy staff comply with the requirements on handling clinical trials supplies.
- The pharmacy site file contains all the required documents.

2 Who Should Use This SOP

This procedure must be followed by all members of the clinical trials team in the Pharmacy department at York and Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust, and any trained member of pharmacy staff who is undertaking this task at a request of a member of the Pharmacy clinical trials team.

3 When this SOP Should be Used

The Sponsor of the clinical trial is responsible for the destruction of returned IMP and/or unused IMP. IMP should therefore not be destroyed without prior written authorisation by the Sponsor.

This SOP should only be used for disposal of any clinical trials materials and IMP that has been accounted for and reconciled.

4 Procedure(s)

4.1 Storage of IMP for disposal

All returned clinical trials IMP and materials (empty or partially empty containers of IMP), and IMP no longer required for the study, including IMP not dispensed and/or expired, must be stored in a specifically allocated area that is access controlled and not accessible to unauthorised persons. Returned clinical trials material must also be stored separately to unused IMP available to be dispensed in the trial.

There are separated areas clearly marked in the Pharmacy departments in York and Scarborough for storage of:

1. returned clinical trials material and IMP (signposted as 'Clinical Trials Returns')
2. IMP no longer required for the study and/or expired IMP (signposted as 'Quarantined stock' (in the clinical trials dispensary and fridges/cold room)

Returned and unused clinical trials IMP should be stored in the original containers.

Damaged containers of clinical trials materials and/or IMP must be kept in the Pharmacy department until these are reconciled then, if agreed, disposed of via a sharps bin or yellow clinical waste bag on site. This must be documented (refer to section 4.4 Destruction of IMP – Records).

For more detail about the storage requirements for IMP and associated quarantine procedures please refer to Pharm/S47 (Storage of Clinical Trial Supplies) and Pharm/S59 (Quarantine of IMP). Further information may also be held in the trial specific Pharmacy site file.

4.2 Accountability checks and recording return of IMP to Pharmacy

When clinical trials materials and IMP are returned to the Pharmacy department, IMP containers and their remaining contents for each clinical trial must be accounted for and documented in the Pharmacy file specific for that study.

Items to be accounted for are:

- Clinical trial Protocol Number and/or EudraCT Number
- Product description (name, strength, form)
- Quantity returned

- Patient numbers (if applicable)
- Batch numbers
- Expiry dates
- Date and initials and/or signature of responsible person.

There is a specific pharmacy procedure in place for each clinical trial in the relevant Pharmacy site file describing how to account for returned clinical trials materials / IMP and relevant documentation to be completed. Refer to Pharmacy site files for specific information as related to each clinical trial. When clinical trials materials and IMP have expired during the study, they will be placed in quarantine. Refer to Pharm/S59 (Quarantine of IMP) for more detail.

A member of the Pharmacy clinical trials team should inform the Sponsor if IMP has expired or has been returned to the pharmacy department so that arrangements can be made for the disposal of the IMP, or return to the Sponsor.

At the end of the study, all clinical trials supplies and IMP not dispensed that are no longer required for the study must be accounted for and kept in the Pharmacy department until these are reconciled. These will then be returned to the Sponsor or destroyed on site depending on the arrangements made at the start of the trial.

4.3 Methods of destruction of IMP

All returned, expired, and unused IMP that are no longer required are either destroyed on site or sent to the Sponsor for destruction. Relevant forms are to be completed to document this activity (see section 4.4).

Each Pharmacy site file will contain information detailing the agreement with the Sponsor on where destruction will occur for the clinical trials materials and IMP for that study.

4.3.1 Returning IMP to the Sponsor for Destruction

The Sponsor may arrange to remove all returned and/or expired IMP at regular intervals during the study. This is usually done by the study Monitor or the study Clinical Research Associate (CRA) during their scheduled monitoring visits.

The study Monitor or CRA will arrange for returned, expired and/or IMP no longer required to be removed.

The study Monitor or CRA is responsible for packing the reconciled IMP and will make suitable arrangements for the collection and disposal of the clinical trials IMP from the Pharmacy department. See Pharm/S55 – Returning Clinical Trial Materials and Investigational Medicinal Product to the Trial Sponsor.

If all clinical trial supplies for a study, including all returned, expired and/or IMP no longer required, must stay in the pharmacy department until the end of that clinical trial study, this should be agreed at the beginning of the study and will be detailed in the Pharmacy site file.

Any relevant forms provided by the Sponsor to document the return of the IMP should be completed by the CRA or a member of the Pharmacy clinical trials team as appropriate, and filed within the Pharmacy site file. If a suitable form is

not provided, one should be designed by a member of the clinical trials team to fulfil the purpose of recording this activity. On return of IMP to the Sponsor for destruction, the accountability logs relating to the study IMP returned must always be updated.

As IMPs may be labelled with the patients name and date dispensed, the patient identity must be removed or blacked out before it is returned to the Sponsor in order to maintain patient confidentiality.

4.3.2 Destruction 'on site'

The Sponsor can request that clinical trials IMP are destroyed on site. In accordance with current York Teaching Hospital NHS Foundation Trust Waste Management Policy and Procedure (& associated Waste Manual) (found on staffroom under 'policies and procedures'), all non-hazardous pharmaceutical waste (i.e. non-cytotoxic or cytostatic medicines) is removed by sending to a contract company for destruction, which is the only destruction process available in the Trust.

Any clinical trials IMP or material classed as cytotoxic and/or cytostatic is defined as Hazardous Pharmaceutical Waste and must also be destroyed in accordance with York Teaching Hospital NHS Foundation Trust - Waste Management Policy and Procedures (& associated Waste Manual) for disposal of cytotoxic and cytostatic medicines and materials contaminated with them. They must be disposed of in suitable leak-proof containers labelled 'Cytotoxic Waste'. Refer to York Teaching Hospital NHS Foundation Trust - Waste Management Policy and Procedures and – Administration of Chemotherapy For Malignant Disease.

Before any clinical trials IMPs are sent for destruction, quantities of IMP must be recorded, accounted for and reconciled for that specific clinical trial. Before sending for destruction, any discrepancies must be investigated, satisfactorily explained and reconciliation accepted (by the Sponsor) for each IMP involved in the clinical trial. All accountability logs relating to the IMP being destroyed must be updated accordingly.

If the Sponsor then requests that clinical trials IMP are sent to the Trust's contract company for destruction, items to be sent for destruction must be placed in an appropriate bag/container depending upon the waste type (refer to York Teaching Hospital NHS Foundation Trust's – Waste Management Policy and Procedure & associated Waste Manual) . The bag/container should be tied/sealed and marked for destruction. These are then collected by porters and placed in the appropriate final storage point (see Appendix 3 of the Trust Waste Manual) and are pre-consigned to go to the Trust's contract company for destruction. The patient identity must be removed from any IMP prior to destruction to maintain confidentiality. Any dispensing labels removed from the IMP must be disposed of in confidential waste.

4.4 Destruction of IMP – Records

All clinical trials IMP sent for destruction 'on site' must be recorded in the relevant Pharmacy site file.

The record of the IMP destruction should clearly identify:

1. Method of destruction – identifying how and when the items have been sent for destruction

2. Name, strength and form of the product
3. Batch numbers and expiry dates
4. Patients numbers involved (only if required), and
5. The actual quantities sent for destruction

The record must be signed and dated by the person sending the clinical trials IMP for destruction, and checked by a second member of the Pharmacy clinical trials team.

The Sponsor may provide documentation for recording clinical trials destruction or the 'Certificate of Destruction' (Pharm/F44) can be used.

This record must include the wording "sent for destruction as per hospital procedure for Clinical Waste".

The Certificate of Destruction should be filed in the Pharmacy site file.

5 Related SOPs and Documents

Pharm/S47	Storage of Clinical Trial Supplies
Pharm/S59	Quarantine of IMP
Pharm/S55	Returning Clinical Trial Materials and Investigational Medicinal Product to the Trial Sponsor
Pharm/F44	Certificate of Destruction

York Teaching Hospital NHS Foundation Trust – Waste Management Policy and Procedures & associated Waste Manual (available on York staff room intra net site)

York Teaching Hospital NHS Foundation Trust – Medicines Code (available on the Horizon intra net site)

York Teaching Hospital NHS Foundation Trust – Administration of Chemotherapy For Malignant Disease

ICH-GCP Guideline for Good Clinical Practice

Practice Guidance on Pharmacy Services for Clinical Trials (RPSGB), June 2005

Annex 13 Good Manufacturing Practice