York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S57

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/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 and/or Q-Pulse

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Author:	Poppy Cottrell-Howe & Sacha Honour
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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:	21st November 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	21st November 2017

This SOP will normally be reviewed every 3 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	8th November 2010	
2.0	17th June 2013	Change of SOP Controller. Addition of Scarborough hospital as a site using this SOP. Minor alterations to the SOP.
3.0	27th July 2015	Minor alterations to the SOP. Change of author.
4.0	19th December 2017	Removal of referenced guidance as these may change and they are not documents pharmacy clinical trials control. Minor alterations made throughout document. Change of author

Contents

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.

Background:

During and at the end of the 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. Destruction or return must only be undertaken 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 site 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 Teaching Hospital NHS Foundation Trust.

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 from the Sponsor.

This SOP should only be used for disposal of clinical trials materials and IMP which have 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 site file specific for that study.

Details to be accounted for are:

- Trial identification
- Product description (name, strength, form)
- Quantity returned
- Patient name/initials/numbers (if applicable)
- Batch numbers and Expiry dates
- Date of dispensing

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.

A member of the pharmacy clinical trials team should inform the Sponsor if IMP has expired or has been retuned 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.

See Pharm/S55 – Returning Clinical Trial Materials and Investigational Medicinal Product to the Trial Sponsor.

4.3.2 Destruction 'on site'

The Sponsor can request that clinical trials IMP are destroyed on site. If this is required local policies and procedures must be followed.

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 local Policy and Procedure). 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 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 Documenting of IMP destruction

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.

Complete a Certificate of Destruction (Pharm/F44) and any Sponsor supplied documentation for recording destruction.

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

Store the Certificate of Destruction in the pharmacy site file.

5 Related SOPs and Documents

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