STANDARD OPERATING PROCEDURE FOR ACCOUNTABILITY, RETURNS AND DESTRUCTION OF INVESTIGATIONAL MEDICINAL PRODUCTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SOP NUMBER:	TASC SOP037 v10
AUTHOR:	Shona Carson
EFFECTIVE DATE:	14 Jan 2024
REVIEW DATE:	14 Jan 2026

1. PURPOSE

This document describes the procedure for accountability, returns and destruction of Investigational Medicinal Products (IMPs) in Clinical Trials of Investigational Medicinal Products (CTIMPs). This Standard Operating Procedure (SOP) complies with the principles of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) (annex 13) and the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

2. SCOPE

Unless otherwise specified in a clinical trial site agreement, this SOP applies to all members of staff associated with and managing clinical research studies sponsored or co-sponsored by the University of Dundee (UoD) or NHS Tayside (NHST).

This SOP is intended for use by UoD staff, NHST staff and other collaborating investigators and their delegates.

3. RESPONSIBILITIES

The Sponsor must maintain records that document shipment, receipt, dispensing, return and destruction of IMPs. These documents are listed as essential documents in the Medicines for Human Use (Clinical Trials) Regulations. The responsibility for IMP(s) accountability at the trial site(s) rests with the Chief Investigator (CI) and the Sponsor. The task of maintaining IMP accountability may be delegated to an appropriate pharmacist or other appropriate individual who is under the supervision of the CI or delegate.

This SOP should be read in conjunction with the other TASC IMP-related SOPs (IMP Manufacturing, Assembly, Packaging & Labelling and IMP Supply, Transport & Storage).

4. PROCEDURE

4.1 Planning and set-up stage of CTIMP

4.1.1 The CI or delegate should have an initial discussion with the Clinical Trials section of Ninewells Hospital Pharmacy Department, (preferably before submission of the grant), to discuss the accountability, return and destruction requirements for the study.

4.1.2 For all UoD/NHST sponsored single-centre CTIMPs, the CI must ensure that all IMP is received by the Clinical Trials Section of Ninewells Hospital Pharmacy Department. For multi-centre studies, the CI should ensure that IMP is received by a pharmacy at each of the sites. IMP and supporting documentation will be checked on arrival, for quality and completeness by pharmacy Clinical Trials staff. This documentation will be filed in the Pharmacy Site File (PSF) and where appropriate a copy will be filed in the Trial Master File (TMF). At any site where PI is maintaining the IMP accountability, this documentation will be filed in the PSF and a copy will be filed in the Investigator Site File (ISF).

4.1.3 All personnel involved in IMP accountability for the CTIMP will be named on the Delegation of Responsibilities log or a Pharmacy Signature log.

4.1.4 The CI or delegate will prepare a trial-specific prescription/IMP request form, if applicable. A blank copy of this form will be filed in the PSF, TMF and/or ISF as appropriate. A prescription/IMP request form will be issued for each participant at each dispensing visit and filed in the PSF.

4.1.5 The CI or delegate will ensure that IMP handling instructions are prepared as a separate document or included in the protocol. These instructions should address adequate and safe receipt, handling, storage, dispensing and retrieval of unused product from participants, return of unused IMP and disposal arrangements for IMP.

4.1.6 Drug accountability forms should be prepared. These forms should allow for the documentation of full drug accountability from arrival of the IMP in the Hospital Pharmacy Department, transfer to a local IMP Storage and Supply Site (if applicable), dispensing to and return from trial participants, through to destruction of used/unused supplies. Alternatively, an electronic IMP management system may be used. The system should be able to generate reports that track each IMP pack.

4.2 During the CTIMP

4.2.1 **General requirements**

Clinical Trials Pharmacy Staff will ensure all regulatory documents are in place prior to any IMP being released for use on trial participants.

The CI or delegate should ensure that the correct use of the IMP is explained to each participant and should check compliance at each study visit.

4.2.2 **Continued management of IMP by Pharmacy**

- All IMP is stored in a secure location, segregated from other medicines. Used and returned medication is kept separate from unused medication.
- Storage conditions are monitored and recorded such that the stability of the IMP is protected. A temperature log is maintained.
- Appropriate IMP labelling is used (see TASC SOP on IMP manufacturing).
- IMP is only dispensed to participants in accordance with the trial protocol and any randomisation list on receipt of a trial-specific prescription or signed request form.
- Participants are reminded to return any unused medication to the trial team.
- Full accountability records are kept for all aspects of IMP handling. Any unused or expired IMP, or IMP returned by participants, will be returned to pharmacy. Disposal will be carried out in an approved manner as defined in the hospital policy covering disposal of pharmaceutical waste. A disposal notice, listing the items disposed, will be prepared by pharmacy and filed in the PSF. No disposal of IMP by investigator team is permitted unless previously agreed by sponsor.
- Sponsor will be notified of any discrepancies in IMP accountability.

4.3 If the CI wishes to use a designated IMP Storage and Supply Site

This should be discussed with the Clinical Trials Pharmacist prior to study start.
Pharmacy will arrange transfer of IMP to local IMP Storage and Supply Sites. The CI will then take responsibility for IMP accountability by ensuring that the tasks listed in 4.2.2 are undertaken by the research team.

The Clinical Trials section of Ninewells Hospital Pharmacy will carry out an annual audit of any local IMP Storage and Supply Site in Tayside.

4.4 On Completion of the CTIMP

The CI or delegate will inform Clinical Trials Pharmacy Staff when a trial has been closed and will ensure that all IMP accountability details for all aspects of IMP handling are archived with the PSF, TMF and ISF, as appropriate.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IMP	Investigational Medicinal Product
ISF	Investigator Site File
NHST	NHS Tayside (Tayside Health Board)
PSF	Pharmacy Site File
SOP	Standard Operating Procedure
TMF	Trial Master File
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
9	Shona Carson (Clinical Trials Pharmacist)	14/01/2022	Biennial review. No changes required.
10	Shona Carson (Clinical Trials Pharmacist)	14/01/2024	Biennial review. No changes required.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	12 Jan 2024