STANDARD OPERATING PROCEDURE FOR SUPPLY, TRANSPORT AND STORAGE OF INVESTIGATIONAL MEDICINAL PRODUCTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

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1. PURPOSE

This document describes the procedure for the supply, transport and storage of Investigational Medicinal Products (IMPs). This Standard Operating Procedure (SOP) complies with the principles of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) [annexe 13] and the UK Medicines for Human Use (Clinical Trial) Regulations.

2. SCOPE

Unless otherwise agreed with Sponsor in writing, this SOP applies to Clinical Trials of Investigational Medicinal Product (CTIMPs) sponsored or co-sponsored by the University of Dundee and/or NHS Tayside (NHST).

Unless otherwise specified in a clinical trial location agreement, this SOP applies to all trial personnel involved in the handling or ordering of IMP.

3. RESPONSIBILITIES

It is the responsibility of the Sponsor, Chief Investigator (CI) or Clinical Trials Pharmacy Staff to ensure that the clinical trial location is supplied with IMP in a timely manner.

The IMP must be supplied, transported and stored at locations in a manner that maintains the integrity of the product at all times. The Sponsor must ensure that documentation is provided and maintained to show that these procedures have been followed.

This SOP should be read in conjunction with TASC SOP37 Accountability, Returns and Destruction of IMP in CTIMPs.

4. PROCEDURE

This SOP should be consulted by research personnel and/or Clinical Trials Pharmacy Staff (preferably before grant submission) for each new CTIMP to ensure early consideration of all issues pertaining to the supply, storage and transport of IMP and that the correct actions are taken.

4.1 Supply of IMP to locations

At the set-up meeting between the CI (or delegate) and Clinical Trials Pharmacy Staff, the IMP supplier, ordering and purchasing arrangements should be discussed.

The IMP supplier or Clinical Trials Pharmacy should not allow the release of IMP to locations until all required regulatory approvals have been obtained.

4.2 Transport of IMP to locations

4.2.1 All IMPs must be delivered to the Pharmacy Department at each trial location for contents and documentation check. Pharmacy Staff should sign a receipt on arrival of IMP, ensure that the IMP packaging is intact and that any special storage conditions such as temperature restrictions have been maintained during transport.

4.2.2 Pharmacy Staff will check the IMP status, any applicable importation documents, and that labelling and approvals are in place before release of IMP.

4.2.3 Shipment documents should be filed in the Pharmacy Site File to confirm date of receipt and storage conditions during transport. All other accompanying documentation (e.g. quantity and batch numbers of IMP delivered, Qualified Person release documents) should be filed in the Pharmacy Site File.

4.2.4 See the TASC SOP37 on Accountability, Returns and Destruction of IMPs in CTIMPs for information on IMP management.

4.2.5 Items 4.2.1 to 4.2.4 apply to IMP transported from manufacturer to Pharmacy Departments. When transferring IMP to IMP Storage and Supply Sites it is important to ensure that optimum storage conditions with respect to temperature, humidity and exposure to light have been maintained throughout the process.

4.3 Transfer of IMP between investigational locations

Transfer of IMP between trial locations should be avoided if at all possible and is only permissible when participant safety is at risk. If it becomes necessary to transfer IMP between locations, consult Clinical Trials Pharmacy Staff and ensure that the transfer process is controlled and documented appropriately.

Delivery of dispensed IMP (i.e. IMP labelled and ready for use) by a member of the research team, either to a clinic covered by Ethics, R&D and regulatory approvals for Tayside or directly to the participant, is not considered as a transfer between investigational locations.

Where such deliveries are anticipated to be necessary in the conduct of a trial, the transfer should be done in a way that protects both the security and integrity of the IMP. Details of the transfer and return of the IMP must be discussed with and agreed by the Lead Clinical Trials Pharmacist for the study and documented in the trial-specific IMP handling guidelines prior to the trial start.

4.4 Storage of IMP at locations - options for storage of IMP

4.4.1 For NHST, IMP will usually be stored in the Clinical Trials Section of Ninewells Hospital Pharmacy Department. IMP may also be stored in a designated IMP Storage and Supply Site if agreed with the NHST Clinical Trials Pharmacy Staff at the planning stage of the CTIMP. For external locations in multi-centre studies, IMP must be stored in a hospital pharmacy or facility equivalent to an IMP Storage and Supply Site. The location of IMP storage should be documented in the Pharmacy Site File, Trial Master File and/or Investigator Site File.

4.4.2 IMP Storage and Supply Sites must be audited annually by Clinical Trials Pharmacy Staff to ensure their suitability for purpose. If an intended IMP Storage and Supply Site has not been audited in the previous year, a pre-trial inspection must be conducted. For external locations in multi-centre studies, evidence of audit by an appropriate person must be available in the Pharmacy Site File and Investigator Site File.

4.4.3 When IMP is stored in an IMP Storage and Supply Site, the CI or local Investigator is responsible for: safe and secure storage of the IMP; strict record keeping; environmental monitoring; and remedial action where necessary. Maximum and minimum temperatures in the storage area should be recorded at least once each week and ideally on each working day. In the event that agreed temperature limits have been exceeded the Investigator must quarantine the affected IMP and seek advice from the Clinical Trials Pharmacy Staff.

4.4.4 There should be a written description of the internal IMP Storage and Supply Site environmental monitoring process included in the IMP handling guidelines and documented evidence that it has taken place.

4.4.5 Where the IMP is stored in Pharmacy Departments, Pharmacy Staff assume the responsibilities for secure storage, record keeping, environmental monitoring, etc. and local Pharmacy SOPs will be followed.

4.5 Considerations for the storage of IMPs

4.5.1 There are important issues related to the storage and supply of medicines (e.g. stability, shelf life and temperature limits) that must be considered by Investigators who store and supply IMPs and Non-IMPs (NIMPs) at IMP Storage and Supply Sites.

4.5.2 Unused IMP should be stored separately from used/returned IMP.

4.6 Security issues

The Medicines Act 1968 sets out the requirements for the storage of medicines in pharmacies and includes clinical trial drugs. Secure storage of IMPs and NIMPs is part of good drug accountability practice.

Important considerations for the storage of IMPs and NIMPs include the use of locked rooms, cupboards, fridges, etc. and the personnel who have access to the location. The following general principles apply:

- During working hours, the IMP Storage and Supply Site should be supervised if not locked at all times. Out of working hours the IMP storage and Supply Site should be locked at all times.

- Only the Investigator and other key members of the research team should routinely have access to IMP Storage and Supply Sites. IMP should not be kept in areas through which there is unrestricted traffic.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IMP	Investigational Medicinal Product
NHST	NHS Tayside
NIMP	Non-IMP
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

TASC SOP 37 Accountability, Returns and Destruction of Investigational Medicinal Products in Clinical Trials of Investigational Medicinal Products

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:**
10	Shona Carson (Clinical Trials Pharmacist)	04/08/2022	No changes required
11	Shona Carson (Clinical Trials Pharmacist)	04/08/2024	No changes required
12	Neil Reynolds (Clinical Trials Pharmacist)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.
13	Neil Reynolds (Clinical Trials Pharmacist)	04/08/2026	No changes required.

8. APPROVALS

Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	29 July 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 July 2026