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 Product (IMP). This 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 (CTIMP) sponsored or co-sponsored by the University of Dundee and/or NHS Tayside (NHST).

Unless otherwise specified in a clinical trial site 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, to ensure that the site is supplied with the IMP in a timely manner, although in the non-commercial setting this responsibility will generally be delegated to the Chief Investigator (CI) or Clinical Trials Pharmacy Staff.

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

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 the 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 the IMP and to ensure that the correct actions are taken.

4.1 Supply of IMP to Sites

At the Set-up Meeting between the CI, or delegate, and the Clinical Trials Pharmacy Staff, the IMP supplier and the ordering and purchasing arrangements should be discussed.

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

4.2 Transport of IMP to sites

4.2.1 All IMP must be delivered to the Pharmacy Department at each site for contents and documentation check. Pharmacy Staff should sign a receipt on arrival of IMP at site and will 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 The Pharmacy Staff will check the IMP status, any applicable importation documents, and that labelling, and all approvals are in place before release of IMP.

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

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 but note that when transferring IMPs 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.

4.3 Transfer of IMP between investigational sites

Transfer of IMP between sites 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 sites, consult Clinical Trials Pharmacy Staff and ensure that the transfer process is controlled and documented appropriately.

Delivery of dispensed IMP (that is, IMP labelled, ready for an individual subject's 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 subject, is not considered as a site-to-site transfer. Where such deliveries are anticipated to be necessary in the conduct of a CTIMP, the transfer should be done in a way that protects both the security and integrity of the IMP. Details of the transfer, and potential 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 Sites - 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. Alternatively, IMP may be stored in a designated IMP Storage and Supply site if this was agreed with the NHST Clinical Trials Pharmacy Staff at the planning stage of the CTIMP. For external sites 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 PSF, Trial Master File (TMF) and/or Investigator Site File (ISF).

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 sites in multi-centre studies, evidence of audit by an appropriate person must be available in the PSF and ISF.

4.4.3 When the IMP is stored in the IMP Storage and Supply Site, the CI/local Principal Investigator (PI) is responsible for the 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 CI 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 the Pharmacy Departments at sites, the Pharmacy Staff assume the responsibilities for secure storage, record keeping, environmental monitoring *etc* and 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 CIs who opt to store and supply IMPs (and Non IMPs {NIMP}) directly from IMP Storage and Supply Sites.

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

4.6 Security issues

The Medicines Act 1968 sets out the requirements for the storage of medicines in pharmacies which also applies to trial drugs stored at trials sites. Secure storage of IMPs (and NIMPs) is thus part and parcel of good drug accountability practice.

Important considerations in the storage of IMPs (and NIMPs) include the use of locked rooms, cupboards, fridges, *etc* and the personnel who have access to the site and the drugs stored therein. 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 CIs 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
ISF	Investigator Site File
IMP	Investigational Medicinal Product
NHST	NHS Tayside
NIMP	Non IMP
PI	Principal Investigator
PSF	Pharmacy Site File
SOP	Standard Operating Procedure
TMF	Trial Master File

6. ASSOCIATED DOCUMENTS & REFERENCES

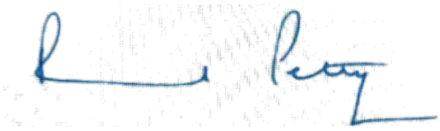
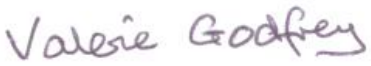
TASC SOP37 Accountability, Returns and Destruction of IMP in CTIMPs

7. DOCUMENT HISTORY

Version Number	Reviewed By (Job Title)	Effective Date	Details of editions made:
History of reviewers prior to 2014 is detailed in the archived SOPs			
5	Shona Carson (Clinical Trials Pharmacist)	04/08/2014	Revised guidance on transfer of IMP between sites and on temperature monitoring.
6	Shona Carson (Clinical Trials Pharmacist)	04/08/2016	Updated to include multi-site trials.
7	Shona Carson (Clinical Trials Pharmacist)	04/08/2018	New TASC SOP template format implemented. Text refreshed and inserted into new format. TASC Policy 01 has been withdrawn and reference to it has been removed from text.
8	Shona Carson (Clinical Trials Pharmacist)	04/08/2020	Revised. Reference to NHS Tayside and NHS Forth Valley removed from section 2.

9	Tracy Petrie (Quality Assurance Support Officer)	25/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
10	Shona Carson (Clinical Trials Pharmacist)	04/08/2022	No changes required.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		02 Aug 2022
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		01 Aug 2022