STANDARD OPERATING PROCEDURE

S45 – TRANSPORTATION OF TEMPERATURE-SENSITIVE MEDICINAL PRODUCTS FOR CLINICAL TRIALS

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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.0	26 February 2012	Clinical Research Nurse Pharmacy CT Manager	New SOP
1.1	20 March 2014	Clinical Research Nurse	Verification regarding current Pharmacy policies
2.0	8 August 2018	Divisional Team Lead & Research Nurse Specialist	Review with significant changes to reflect incorporation of wider scope and inclusion of multiple medicinal products used in clinical trials
3		Lead Research Nurse	Overall review and update of SOP auditing process.

Associated Trust Policies/ Procedural documents:	Transfer of MP from the Clinical Trials Office to ASU or Clinical Areas' CTR034 RDE Pharmacy SOP (not available on the RDEResearch website – paper based and available in clinical trials pharmacy).
Key Words:	Medicines management Clinical trials Temperature-sensitive Medicinal Products Transportation
In consultation with: Research & Development – Quality Assurance Group - July 2021 Research & Development Governance and Oversight Group (GOG) – August 2021	

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1 INTRODUCTION

Some Medicinal Products (MPs) used in clinical trials require storage within specific temperature ranges. This range is defined within the manufacturer's guidelines. Storage outside these ranges can result in the reduced efficacy of the drug. Maintaining a cold chain refers to the procedures necessary to ensure that a temperature-sensitive medicine is stored and transported within the correct temperature range specified by the manufacturer and study protocol, and providing evidence of maintenance of temperature control during transportation between sites as required. Guidelines for the specific temperature range and other storage conditions for MPs should be according to those set out in each study protocol and study reference manual (SRM).

2. PURPOSE

This standard operating procedure (SOP) is to establish the principles to ensure that a record of this temperature control is maintained during storage and transport of temperature-sensitive MPs used in clinical trials.

3. SCOPE

This document is to be used by all research staff when dealing with the transportation of temperature-sensitive MPs used in clinical trials, between and within Trust sites, and to participant homes.

4. DEFINITIONS

CIVAS	Centralised Intravenous additive services
CT	Clinical Trial
GOG	R&D Governance and Oversight Group
IB	Investigational Brochure
R&D	Research & Development
RD&E	Royal Devon & Exeter
MPs	Medicinal Products
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SRM	Study Reference Manual

5. DUTIES AND RESPONSIBILITIES OF STAFF

Pharmacy Clinical Trials Manager

It is the responsibility of the Pharmacy Clinical Trials Manager to ensure that temperature-sensitive MPs received for trials are suitable for use in the trial.

The Pharmacy Clinical Trials Manager must ensure that suitable packaging and temperature monitoring equipment e.g. thermometers are available.

Trials Staff

It is the responsibility of clinical trials staff to ensure that temperature-sensitive MPs are packed ready for transport according to the procedures set out in this SOP and are appropriate to the specific guidelines of the study protocol.

It is the responsibility of the nurse or registered practitioner who has been delegated the responsibility of administering the MP to ensure that it is transported correctly according to the procedures set out in this SOP and that these are compatible with

the requirements of the study specific protocol and/or Investigator Brochure (IB) and/or Summary of Product Characteristics (SmPC).

Only those staff who have received study specific training and been delegated the responsibility should collect and transport temperature-sensitive MP. It is the responsibility of all clinical trials staff involved with the administration of an MP to read this SOP before participating in the trial.

6. PROCEDURES

For the storage and handling of temperature-sensitive MPs on Royal Devon & Exeter (RD&E) Trust Sites, please refer to the R&D clinical Trials SOP 'Transfer of MP from the Clinical Trials Office to ASU or Clinical Areas' CTR034 RDE Pharmacy SOP.

6.1 Transporting temperature-sensitive MPs

A suitable cool pack/box must be used for transporting temperature-sensitive MPs requiring cold storage. A domestic cool box should not be used for storage, distribution or transportation. Where MP is transported in a vehicle, e.g. on a home visit, cool packs/boxes should be transported in the boots of cars, not on car seats.

MPs must be kept in original packaging, and transported in accordance with manufacturer's guidelines and in compliance with study protocols. The time between removing MPs from cold storage and use must be kept to a minimum.

A maximum/minimum calibrated temperature probe, or a temperature recording device provided or approved by the Sponsor should be placed in the middle of the cool pack/box and must remain inside the cool pack/box for the duration of the journey, with the display panel visible outside the box.

The temperature of the container must be checked and be within the required range prior to leaving Pharmacy, and again upon arrival at destination prior to administering the medication. Depending on individual sponsor instructions a written log of temperatures at the start and end of the transport may be recorded.

If the temperature has not remained within the required range at any time in the transport process the MP must not be administered. Contact the Clinical Trials Pharmacy Department for advice as to next steps.

6.2 Unused or damaged temperature-sensitive MPs

If a temperature-sensitive MP appears to have been damaged it must not be administered and should be returned unused to the Clinical Trials Pharmacy Department who will advise what action is needed.

If an MP is not dispensed for clinical reasons, it should be returned to the Clinical Trials Pharmacy Department in the cool box with the cold chain maintained if possible, and returned to the Clinical Trials Pharmacy fridge as quarantined stock.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Only those staff who have received study specific training and been delegated the responsibility should collect and transport temperature-sensitive MP.	Study delegation of duty log and staff training log held in the TMF/ISF/eTMF.
2.	The temperature of the container must be checked and be within the required range prior to leaving Pharmacy and again upon arrival at destination prior to administering the medication.	A written log of temperatures recorded at the start and end of the transport.
3.	Damaged or not dispensed temperature-sensitive MP should be returned to the Clinical Trials Pharmacy Department.	Clinical Trials Pharmacy Department study specific log.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES