STANDARD OPERATING PROCEDURE FOR TEMPERATURE MONITORING OF INVESTIGATIONAL MEDICINAL PRODUCTS STORED OUTSIDE PHARMACY

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1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for temperature monitoring of Investigational Medicinal Products (IMPs) stored outside the Pharmacy Department.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Department via fife-uhb.randd@nhs.net).

2. APPLICABILITY

This SOP applies to all research personnel involved in Clinical Trials of Investigational Medicinal Products (CTIMPs) in NHS Fife including Principal Investigators (PIs), Research nurses and the Clinical Trials Pharmacy Team.

3. POLICY

3.1 The National Pharmacy Clinical Trials Advisory Group Professional Guidance on Pharmacy Services for Clinical Trials (2013) states that *'where clinical trials take place in a hospital, all IMPs should be stored and dispensed by the hospital pharmacy and managed to the same standards as licensed medicines, in accordance with local medicines management policy. Whenever possible, IMPs should be stored in the pharmacy. However, it may be necessary to store IMPs on wards or in other departments (for example, if IMPs are to be used in emergency situations or for inpatients). If IMPs are to be stored outside of the pharmacy a risk assessment should be performed'*.

Storage of IMP in locations outside of the Pharmacy Department may be necessary for only short periods of time between the item being dispensed by the Pharmacy Department and being administered to patients or for longer periods when it is not practical for the Pharmacy Department to dispense IMP to individual trial patients. Examples include trials where a patient may receive treatment outside of the Pharmacy Department opening hours, or where treatment may be required immediately (e.g. in the Genito-Urinary Medicine (GUM) clinic or Accident and Emergency Department), where the time interval between the diagnosis and IMP administration could be short.

3.2 Investigational Medicinal Products (IMPs) must be kept securely in a locked cupboard, fridge or freezer within the temperature ranges specified by the trial Sponsor and drug manufacturers.

3.3 The proposed facilities for storing IMP outside of the Pharmacy Department require assessment and approval by the Clinical Trials Pharmacist or delegate prior to confirmation of Pharmacy support of the study and prior to full Local Management Approval being issued (see CTPSOP 18 - Procedure for Carrying out a Pharmacy Check of IMP that is to be Stored and Dispensed by the Investigator). A member of the Pharmacy Clinical Trials Team will confirm if any actions require to be taken based on the outcome of this assessment in line with the Sponsor stipulations for IMP storage.

3.4 Where temperature monitoring is required, temperature logs must be kept to document that the appropriate temperature range has been maintained. If the Sponsor has not supplied a study specific temperature monitoring log then Doc Ref WI13-01 - Temperature Log must be used.

3.5 Temperature Specifications:

- Ambient/room temperature 15-25ºC (or maximum 30ºC on selected IMPs)
- Fridge temperature 2-8ºC
- Freezer temperature <-15ºC

Certain IMPs may require storage between different temperature ranges. In these cases, the storage conditions listed on the IMP label and in the protocol should be followed.

3.6 The PI may delegate responsibility for temperature monitoring and recording to a member of the research team or a member of staff working in the clinical area, a deputy must also be nominated in their absence to ensure this is completed.

4. PROCEDURE

4.1 Temperature monitoring must be carried out using a calibrated data logger that will allow the recording of temperatures at 5 minute intervals as a minimum. When used with a refrigerator or freezer, the probe should be positioned in the middle of the storage device amongst the IMP. The probe must not rest on, or be near the light and must not be placed near the door.

4.2 For each area that requires temperature monitoring, the current temperature (either ambient and/or refrigerator and/or freezer) must be recorded once daily on each working day (Monday – Friday excluding bank holidays) along with the minimum and maximum temperature since the previous check.

4.3 If possible, dependent on the type of thermometer in use, the graphical records of temperature should be printed off at the start of each month and examined by a member of the Research Team for temperature excursions in addition to the daily check. If there are no excursions a note must be added to confirm this and the document signed and dated.

4.4 In the event of a temperature excursion the following actions should be taken;

4.4.1 The Clinical Trials Pharmacy Team must be contacted as soon as possible, to clarify if the IMP can be quarantined within the current storage area and if required, to arrange transfer of the IMP back to the Pharmacy Department for quarantine.

4.4.2 If quarantine in the current storage area is appropriate, affected IMP must be placed in a container clearly marked 'in quarantine' and kept separate from non quarantined IMP in the required storage location (locked cupboard/fridge/freezer).

4.4.3 Details of the temperature data should be obtained from the data logger for each excursion, confirming how long the IMP has been outside the required range and the temperature range during the excursion period.

4.4.4 For each IMP involved, the trial Sponsor must be contacted by a nominated member of the Research or Clinical Trials Pharmacy Team to seek guidance on the actions to be taken.

4.4.5 IMP must remain in quarantine until direction from the Sponsor has been received.

4.4.6 The storage area must be investigated by a member of the Research Team identify the cause of the excursion and resolve any issues.

4.4.7 If advised, IMP must be destroyed as per Sponsor specification and CTPSOP 08.

4.4.8 If advised, IMP can be released from quarantine and if applicable, returned from the Pharmacy Department to the designated storage area if this has returned to within an acceptable range for a minimum of 24 hours.

5. ASSOCIATED DOCUMENTS

Doc Ref WI13-01 - Temperature Log
CTPT 01 - Risk Assessment for CTIMP Storage Out-With Pharmacy
CTPSOP 08 - Clinical Trial Material Destruction and Waste Disposal
CTPSOP 18 - Completion of Risk Assessment on CTIMP Storage Area Out-With Pharmacy

6. DEFINITIONS / ABBREVIATIONS

CI Chief Investigator
IMP Investigational Medicinal Product
PI Principal Investigator
R&D Research and Development
SOP Standard Operating Procedure

7. REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

National Pharmacy Clinical Trials Advisory Group (NPCTAG) Professional Guidance on Pharmacy Services for Clinical Trials (version 1.0, October 2013)

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	08 June 2018	N/A – new SOP
2	Jennifer Tait Senior Clinical Trials Pharmacist	25 May 2020	Reformatted in line with current SOP template. Referenced Clinical Trials Pharmacy SOPs updated. Text refreshed throughout for clarity.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	18 May 2020