STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_021

SOP Title: Room temperature monitoring of clinical trial medication storage area

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		02-MAR-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		08-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	05-Aug-2016	V.1- Initial Version	
2	1-June-2018	Reviewed to ensure content still current. Added additional information about not requiring air conditioning and drug storage outside of 15-25C range if agreed by sponsor in writing.	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_021

SOP Title: Room temperature monitoring of clinical trial medication storage area

1. PURPOSE AND CONTEXT

1.1. To describe the procedures for temperature monitoring the storage areas for clinical trial medication.

1.2. This SOP should be read in conjunction with Trust Policy SH CP 87: Temperature Management of Medicines Storage and Transport. The principles of good temperature management are covered in Policy SH CP 87: this SOP provides direction where management of clinical trial products varies from handling medicines elsewhere in the Trust.

1.3. This SOP covers the storage area (room). See SOP CP/R&D_025 for the procedure to manage refrigerated clinical trials, including fridge temperature monitoring.

2. DEFINITIONS

IMP – Investigational Medicinal Product

3. PROCEDURE and RESPONSIBILITIES

3.1 IMPs requiring room temperature storage may only have stability data to show they can be stored between 15-25C. Some IMPs may be stored outside of this range where it is agreed with the sponsor in writing.

3.2 Store the IMPs, in a secure area and within the temperature parameters specified for the product.

3.3 The room temperature in this area is maintained by an air-conditioning unit and a log of the maximum and minimum temperatures of the area is documented daily Monday to Fridays except for bank holidays. In exceptional cases, a sponsor may agree for a trial to be stored in a non-air-conditioned room outside of pharmacy. In this case, this approval must be in writing and temperature must be recorded daily Monday to Fridays.

3.4 The thermometers are checked and temperatures recorded, the thermometer must then be reset.

3.5 Any temperature deviations below 15 degrees or above 25 degrees Celsius in the room or cupboard thermometer should be reported to the sponsor/monitor, clinical trials pharmacist and research manager. The exception to this is if it is specifically agreed in writing from the sponsor that an IMP may be kept outside of this range, in which case a deviation outside the agreed parameters must be reported; for example some drugs may be stored at up to 30 degrees Celsius depending on drug stability data.

3.6 Quarantine the IMP. See SOP CP/R&D_012 Quarantining of investigational medicinal products

3.7 Complete the Temperature Deviation Log with the following details:

- Log number – allocate next consecutive number
- Date of temperature deviation
- Location of temperature deviation

- Clinical trials affected by the temperature deviation
- Confirmation that the IMP has been quarantined
- Name of sponsor/monitor contacted
- Outcome when known – If IMP is suitable for use or not

3.8 Enter the temperature deviation log number on the temperature monitoring log form. Also ensure any sponsor required paperwork relating to the deviation is completed.

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Ensure correct procedures are followed
2	Clinical Trials Pharmacist	Staff involved with the day to day management of IMP's	Temperature monitoring, reporting of temperature deviations and completing the temperature deviation log
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 1 Medicines Control, Administration and Prescribing Policy
- CP/R&D_012 SOP - Quarantining of investigational medicinal products
- CP/R&D_025 – Refrigerated clinical trials
- Form 17 – MARC & R&D Temperature Monitoring Log
- Form 18 – Temperature Deviation Log

5. TRAINING

- ICH-GCP guidelines
- An understanding of trial legal requirements needed before commencement of trial.
- An understanding of managing temperature deviations in each trial

6. REFERENCES