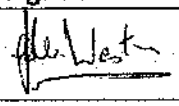
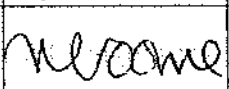
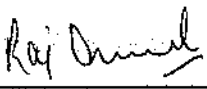
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_025

SOP Title: Refrigerated clinical trials

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		05/03/18
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	08-Jul-2016	Initial Version	18/07/16
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1. To describe the procedures for managing refrigerated clinical trials products.

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.

2. DEFINITIONS

3. PROCEDURE and RESPONSIBILITIES

3.1 Procedure for receipt of refrigerated clinical trials products

3.1.1 Only staff confident in handling refrigerated clinical trials products who are also on the relevant delegation log for handling the trial product may accept deliveries.

3.1.2 The staff member accepting the delivery must immediately move the delivery to a secure location.

3.1.3 The medication must be receipted following the "drug receipt instructions" for the relevant trial (found in the pharmacy working documents files).

3.1.4 If the staff member accepting the delivery cannot complete the entire receipt procedure (for example if he does not have access to the interactive web response system [IwRS]), then find a staff member who is able to do this. If no-one else is available to help, the following minimum applies:

a) Stop the continuous temperature monitor (following instructions in the delivery/drug receipt instructions).

b) Clearly label the delivery as "quarantined".

c) Put the delivery and temperature monitor in the correct fridge for that trial. Do not overfill the fridge (see 3.1.5)

d) Inform the clinical trials pharmacy team of the delivery and what has been done so far.

3.1.5 Arrange all stock neatly in order before putting in a fridge to ensure it can be found quickly. **Do not overfill a fridge**. A fridge must be no more than half full and air must be able to

circulate around the back, sides, top and bottom of the fridge interior and between shelves. Do not use the bottom of the fridge or salad box for storing investigational products. See section 3.3.3.

3.2 Procedure for monitoring clinical trial fridge temperatures

3.2.1 Clinical trials fridges monitored using only the integral "min/max" thermometers must be checked daily (except for weekends and bank holidays) and temperature recorded using the *'Refrigerator temperature monitoring sheet' (Form 14)*. Copies of these records must be kept in the pharmacy files of studies for which the fridge was used.

3.2.2 Clinical trials fridges monitored using continuous USB thermometers must be checked on a daily basis (excluding weekends or bank holidays) to ensure that the probe has not recorded any deviation. Download data from the USB thermometer as frequently as required by trial sponsors, at no longer than monthly intervals. Record the current fridge temperature (according to the USB thermometer) and sign the recording log *'Refrigerator temperature monitoring sheet'* (Form 14) each day. Keep this record with any printouts from the thermometer. Copies of these records must be kept in the pharmacy files of studies for which the fridge was used. It is unnecessary either to record minimum or maximum temperatures using the integral fridge thermometer or to reset the integral fridge thermometer.

3.3 Managing temperature excursions

3.3.1 The risk of temperature excursions must be minimised.

3.3.2 Identify the required products before opening the fridge door. Do not open the fridge door and spend a long time locating the kit needed.

3.3.3 From practical experience, do not open a fridge door for more than **15 seconds** in a period of **30 minutes**.

3.3.4 Temperature excursions must be managed following SOP 027 - Fridge temperature deviations

3.4 Responsibilities

3.4.1 The clinical trials pharmacist is responsible for maintaining the cold chain. The clinical trials technician is the nominated deputy.

3.4.2 All staff involved in clinical trials using refrigerated medicines must be aware of the contents of this procedure.

3.4.3 All staff involved in clinical trials using refrigerated medicines must be aware of how to manage temperature deviations.

	Responsibility	Undertaken by	Activity
1	Clinical trials pharmacist	Clinical trials pharmacist, clinical trials technician, other authorised members of the site team	The clinical trials pharmacist has overall responsibility for maintaining the cold chain but may delegate some tasks to other authorised members of the site team

4. SUPPORTING MATERIAL and ATTACHMENTS

- Trust Policy SH CP 87: Temperature Management of Medicines Storage and Transport
- R&D SOP 027: Fridge temperature deviations
- Refrigerator temperature monitoring sheet (Form 14)

5. TRAINING

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

6. REFERENCES