STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_027

SOP Title: Fridge Temperature Deviations

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		05/03/2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		08-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		Effective date stamp

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	August 2016	Initial version	
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_027

SOP Title: Fridge Temperature Deviations

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the procedures to be taken by staff in the event of there being temperature deviations on the fridges containing Investigational Medicinal Products (IMPs).

1.2. A temperature excursion is defined as temperature outside the range of 2°C to 8°C, discovered either using the integral fridge thermometer (when used alone) or a continuous USB thermometer. In rare cases a study may have specific temperature parameters which differ from this. Please refer to individual study protocol.

1.2.1. If the integral fridge thermometer shows a deviation outside this range but a continuous USB thermometer on the same fridge remains within range, the USB thermometer data overrides the integral fridge thermometer.

1.2.2. If the integral fridge thermometer does not show a deviation outside this range but a continuous USB thermometer on the same fridge does, the USB thermometer data overrides the integral fridge thermometer.

2. DEFINITIONS

N/A

3. PROCEDURE and RESPONSIBILITIES

3.1. In the event of a temperature deviation on any of the fridges containing IMPs an alarm will sound. If this happens then you must refer to the labels on the fridge to identify which trials have been affected.

3.2. Move all stock in the affected fridge immediately to a non-affected fridge, clearly separated from all other stock. Clearly mark this stock as quarantined (see SOP CP/R&D_012).

3.3. Refer to the protocol/pharmacy manual/monitor for specific information on managing the deviation.

3.4. Within 30 minutes of the alarm sounding (or when the deviation is discovered), send an urgent email to the study coordinators outlining what happened and the action taken. Copy in the clinical trials pharmacy team, the sponsor representative

for the study, and any other person required to be informed by the study requirements.

3.5. Do not issue the stock to a patient unless the quarantine is lifted by both the trial sponsor and the clinical trials pharmacy team (see SOP CP/R&D_012).

	Responsibility	Undertaken by	Activity
1	R&D/MARC Office	All R&D/MARC staff members	Responding to the alarming fridge.
2	R&D/MARC Office	All R&D/MARC staff members	Alerting the clinical trials pharmacist of the deviation and following the instructions for ensuring the deviation is managed correctly.
4	Chief Pharmacist	Clinical Trials Pharmacist	Ensure correct procedures are followed
3	Clinical Trials Pharmacist	Research nurses, Research assistants, Pharmacy technician	Temperature monitoring and reporting temperature deviations

4. SUPPORTING MATERIAL and ATTACHMENTS

- CP/R&D_012 Quarantining of Investigational Medicinal Products
- CP/R&D_025 Refrigerated clinical trials

5. TRAINING

N/A

6. REFERENCES

N/A