

## Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	<b>17.006</b>	Version	<b>5.0</b>
Title	<b>Refrigerator and Freezer Unit Use and Monitoring</b>		

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SOP category	17 NHS GG&C Clinical Research Facility – Clinical				
Staff category	<b>Staff Category</b>	<b>R</b>	<b>A</b>	<b>C</b>	<b>I</b>
	Nursing	X			
	GCRF Manager		X		
	Site Clinical Trials Pharmacy				X
	GCRF Associate Director				X
	Senior R&I Manager				X

### 1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

### 2. Purpose

To outline the use and maintenance of refrigerator/freezer units for clinical purposes located within GCRF.

### 3. Procedures

#### 3.1. Equipment Use

- All refrigeration/freezer units used for clinical purposes e.g. drug or sample storage must be regularly inspected and kept clean.
- All reagents, biological samples, tissue samples or any substances requiring refrigeration or freezing will be placed in an appropriate container to prevent the possibility of spills, leakage, odours or spoilage prior to storage in a refrigerator/freezer unit.
- All reagents, biological samples or any substance stored in a refrigerator or freezer must be appropriately labelled complying with relevant policies and documentation.
- Study specific sample log or Form 17.041A Sample Log must be completed and updated at time of storage and shipment.
- Form 17.041B – Fridge and Freezer Planner must be updated when samples are added or removed.
- Explosive, flammable or corrosive substances must be stored in laboratory refrigerators specifically designed for that purpose.

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### 3.2. Equipment Monitoring

- Kelsius System and Checkit Temperature Monitoring Systems are used by GCRF to continually monitor fridge and freezer temperature. Both systems will alarm and alert nominated GCRF staff by email and text following temperature excursions out with set ranges. GUI 17.006B Kelsius Monitoring System, GUI 17.006C Checkit Monitoring System and GUI 17.006A Out of Hours Fridge and Freezer alert must be followed.
- Following SOP 17.041 Sample Management, clinical staff are responsible for monitoring and maintaining contents of clinical use refrigerators and freezers located within the CRF.
- Minimum and maximum temperature range will be electronically recorded and monitored.

### 3.3. Maintenance

- Clean unit in compliance with manufactures instructions and GG&C Infection Control policy.
- Annual maintenance is conducted by licensed contractors and records maintained for inspection.
- Any additional maintenance/service should be performed by authorised personnel and unit re-certified in writing.

### 3.4. Freezer Deviation and Failure

In the event of a temperature deviation:

- Weekdays 0800-1700 hours excluding public holidays – GCRF Nurse Coordinator will respond to the alert as detailed in GUI 17.006B and GUI 17.006C. Nurse Coordinator must inform a Research Nurse Manager.
- Weekdays 1700-0800 and weekends including public holidays – On-call Research Nurse Manager will respond to alerts following GUI 17.006A Out of Hours Fridge and Freezer Alerts.

### 3.5. Drug Fridge Deviation and Failure

In the event of a temperature deviation where the drug fridge registers out-with the recommended temperature, medicines should be moved temporarily to another fridge. Pharmacy must be informed, and appropriate action taken as recommended by pharmacy.

Where medication stored is an Investigational Medicinal Product and there are any temperature deviations the sponsor and pharmacy must be informed immediately, and appropriate action taken.

## 4. Referenced documents

- GUI 17.006A – Out of Hours Fridge and Freezer Alert
- GUI 17.006B – Kelsius Monitoring System
- GUI 17.006C – Checkit Monitoring System
- SOP 17.041 – GCRF Sample Management
- Form 17.041A – Sample Log
- Form 17.041B – Fridge and Freezer Planner
- NHS GG&C Infection Control Policy

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### 5. Related documents

- Manufacturer's Instructions
- Sample logs (study specific)
- GUI 22.008B – Standards for Refrigerators and Freezers and Temp Monitoring Equipment for Clinical Trials
- SOP 17.034 – Storage and Management of Medication

### 6. Document history

Version	Date	Description
Draft	04/09/07	Creation of SOP
1.0	22/11/07	Release of Version 1
1.1	19/05/08	Released to staff
1.2	30/09/09	General update
2.0	25/11/13	Author change, significant changes to provide clearer guidance on use and monitoring of fridges and freezers
2.1	25/02/14	Minor changes to procedure and addition of section 5.5
3.0	15/07/16	SOP restructure Update to SOP template v1.4 Minor admin changes
4.0	18/12/2018	Reference to SOP 17.041 Sample Management Additional guides – GUI 17.006A, GUI 17.006B, GUI 17.006C
5.0		Update to SOP template v2.0 Addition of RACI matrix Tutela references changed to Checkit

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