

Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	17.034	Version	5.0
Title	Storage and management of medication		

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Released by Signature	Julie Brittenden	Date

SOP category	17 NHS GG&C Clinical Research Facility – Clinical				
Staff category	Staff Category	R	A	C	I
	Nursing	X			
	Principal Investigator	X			
	Clinical Research Fellow	X			
	Site Clinical Trials Pharmacy	X			
	GCRF Manager		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

The purpose of this procedure is to describe the process for the safe storage of medications within GCRF.

3. Procedures

NHS GG&C Safe and Secure Handling of Medicines Policy require that medicines should be stored at a level of security appropriate to their category and proposed use at all times. The nurse in charge of the clinical area is responsible for ensuring all medicines are in locked cupboards or locked fridges approved by pharmacy.

3.1. Storage of medication

Investigational Medicinal Product (IMP) must be clearly identified as IMP in the study specific drugs cupboard or if appropriate in the drug fridge.

Medicines must be stored in alphabetical order as far as practically possible, ensuring the label remains legible and where possible in the original packaging received from pharmacy.

Medications should be segregated if possible according to route of administration to minimise drug administration errors.

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Stock levels must be maintained to meet department needs, and documented on Form 17.034A
Stock medications are ordered as necessary to maintain stock levels and meet new study needs by a registered nurse or midwife using the appropriate pharmacy documentation.

Medication expiry dates will be checked weekly and recorded by a registered nurse on Form 17.034A.

Stock should be rotated in order for old stock to be used first.

Monthly spot checks of the medication cupboard will be conducted by a research nurse manager and recorded in the relevant documentation (Form 17.032A).

3.2. IMP Involving the Pharmacy Aseptic Unit

If the product requires aseptic preparation the Site Clinical Trials Pharmacy Team should be notified as soon as possible. Trials team must always send prescriptions directly to Site Clinical Trials Pharmacy for professional check. Once professional check completed, the pharmacist will send the prescription to the RHC Pharmacy Aseptic Unit for preparation.

Any IMP prepared within the RHC Pharmacy Aseptic Unit must be transported to the appropriate area via the approved method discussed during study set up.

3.3. Monitoring and Management of temperature

Drug cupboard temperatures are monitored constantly by the Kelsius system and temperature records are stored on the Kelsius online database. Significant temperature excursions will result in site staff being alerted. If there are any temperature deviations out with the defined range, the medicines should be moved temporarily to another appropriate storage area. Pharmacy must be informed and appropriate action taken as recommended by pharmacy.

Where medication stored is an IMP and there are any temperature deviations the trial Sponsor and pharmacy must be informed immediately and appropriate action taken.

4. Referenced documents

- Form 17.034A – Drug cupboard weekly checklist
- Form 17.032B – Nurse Manager Drug Cupboard Spot Check
- Form 17.032A – Spot check record
- NHS GG&C Policy – Safe and Secure Handling of Medications in Hospital Wards, Theatres and Departments

5. Related documents

None

6. Document history

Version	Date	Description
1.0	02/07/2012	Release of 1 st Version
2.0	25/11/2013	significant changes to provide clearer guidance on management of medicines, change of author
2.1	25/02/2014	Minor changes within section 5.2 and references.

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Version	Date	Description
3.0	15/07/16	SOP restructure Update to SOP template v1.4 Minor admin changes Removal of manual temp monitoring, monitored and recorded automatically Change to approved and released by
4.0	26/08/2019	Minor changes to staff responsibilities in section 5.1, removal of related document and inclusion of drug fridge in section 5.2
5.0	18/08/2023	Update to SOP template v2.0 Addition of RACI matrix Change of author Minor admin changes Addition of aseptic unit Addition of Form 17.034B

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