**Glasgow Clinical Trials Unit Standard Operating Procedure**

| SOP number | **17.032** | Version | **4.0** |
|---|---|---|---|
| Title | **Return of stock drugs and IMP** | | |

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| Prepared by<br>Signature | Barbara McLaren<br>Date |
| Approved by<br>Signature | Lynn Prentice<br>Date |
| Released by<br>Signature | Julie Brittenden<br>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 | | | |
| | 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

This procedure applies to all clinical staff within GCRF.

## 3. Procedures

### 3.1. Stock drugs

NHS GG&C Safe and Secure Handling of Medicines in Hospital Wards, Theatres and Department requires that medicines should be stored at a level of security appropriate to their proposed use at all times. The nurse in charge is responsible for ensuring all medicines are in locked cupboards or locked fridges approved by pharmacy.

The drugs in each area will be checked and documented in Form 17.034A. In addition, spot checks will be conducted by a Research Nurse Manager and recorded in Form 17.032A.

Expired or non-required drugs must be disposed of in clinical waste or appropriate sharps bin.

### 3.2. Investigational Medicinal Product

The return and recording of IMPs used in a clinical trial, including empty packaging, is required for drug accountability, destruction, and monitoring participant's compliance and safety purposes.

At each trial visit the research team should count the medication and packaging returned by the participant and record in the trial documentation. It must also be recorded in the trial documentation when no medication or packaging is returned at the trial visit.

3.2.1. During pharmacy working hours

The returned items should be taken by GCRF staff to the clinical trials pharmacy which dispensed the IMP and recorded in the trial documentation.

3.2.2. Outside pharmacy working hours

Where the returned items cannot be taken to the dispensing pharmacy, it should be locked in the study medication returns cabinet and recorded in the study documentation. Items will be returned on the pharmacy's first working day.

The member of GCRF staff delegated to complete the weekly checks will inform the study team if there are items present in the IMP returns cupboard. The study nurse or designee will arrange for the IMP to be returned to the site pharmacy.

## 4. Referenced documents

- NHS GG&C Safe and Secure Handling of Medicines in Hospital Wards, Theatres and Department
- Form 17.032A – GCRF Spot Check Rota
- Form 17.034A – GCRF Drug Cupboard

## 5. Related documents

None

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 15/05/13 | First release |
| 1.1 | 25/11/13 | Minor changes to provide guidance on spot checks |
| 2.0 | 15/07/16 | SOP restructure<br>Merged with SOP 17.033<br>Updated to SOP template version 1.4.<br>Updated approved and released by |
| 3.0 | 26/08/2019 | Periodic Review and minor changes for clarification in 5.2.2 |
| 4.0 | 18/08/2023 | Update to GCTU SOP template v2.0<br>Addition of RACI matrix |