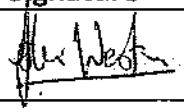
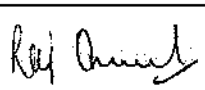
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_018

SOP Title: Processing of returned clinical trial medication

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		07-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**	Effective date:	

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	12-Jan-2016
3	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_018

SOP Title: Processing or returned clinical trial medication

1. PURPOSE AND CONTEXT

1.1 To describe the procedures for processing returned clinical trial medication.
1.2 Covers the procedures to follow for the receipt, reconciliation and storage of clinical trial medication returned from participants. Procedures for processing clinical trial medication stock returned from ward/clinic are also included.

2. DEFINITIONS

IxRS – Integrated phone and web drug management system.

CRA – Clinical research associate. Usually a commercially employed person supporting the management of clinical studies, helps with obtaining R&D approval, site initiation, study monitoring and close out.

3. PROCEDURE and RESPONSIBILITIES

- As part of the trial review and set up process, ascertain the requirements for returned clinical trial medication, and document the agreed process in the trial specific pharmacy instructions.

3.1 Receipt of clinical trial medication returned from participants

3.1.1 On receipt of clinical trial medication returned from participants (or indirectly via investigators/nurses), place all items including any empty boxes and any accompanied documentation in a sealable bag.

3.1.2 Mark the sealed bag with your name and the date of return.

3.1.3 Place the sealed bag in appropriate returns cupboard for that trial.

3.2 Reconciliation of returned clinical trial medication from participants

3.2.1 Locate the relevant pharmacy site file and follow the trial specific procedures on reconciliation of returned clinical trial medication. This may include:

- Following safety instructions on personal protective equipment
- Counting and recording of returns on the accountability log
- Logging of returns on IxRS (interactive voice/web response system) by following sponsor's instructions as applicable.

3.2.2 If the returned clinical trial medication has been dispensed by another site, quarantine the clinical trial medication and notify the relevant sponsor or pharmacy immediately.

3.3 Storage of returned clinical trial medication from participants

3.3.1 After reconciliation, place the returned clinical trial medication in the relevant trial specific return cupboard and retain until verified by sponsor.

3.3.2 Where retaining of returned clinical trial medication is not required as specified in the trial specific pharmacy instructions, follow the procedures for disposal/destruction of clinical trial medication SOP (CP/R&D_009)

3.3.3 Clinical trial medication returned from participants should never be used for another trial participant.

3.4 Processing clinical trial medication stock returned from ward/clinic

3.4.1 For trials where stock of clinical trial medication is held on ward/clinic level, the arrangement for returning used or unused clinical trial medication should be agreed at the trial set up stage with the agreed process clearly stated in the trial specific pharmacy instructions.

3.4.2 The arrangement should be made so that the research team contacts a member of the core pharmacy clinical trial team directly on a scheduled basis.

	Responsibility	Undertaken by	Activity
1	Sponsor	Study monitor or Clinical research associate.	The sponsor of the trial is responsible for the disposal of the returned and unused IMP. The study monitor or CRA will act on behalf of the sponsor
2	Clinical Trials Pharmacist	Research nurse and Pharmacy staff	Complete the paperwork and prepare the IMP for disposal / destruction.
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Disposal/destruction of clinical trial medication form (Form 04)
- CP/R&D_009: Disposal/destruction of clinical trial medication SOP

5. TRAINING

Knowledge of the Clinical Trial Protocol is essential as specific instructions regarding the destruction of the drugs may be detailed in the Protocol and may vary between trials

6. REFERENCES