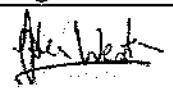
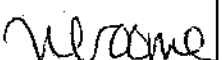
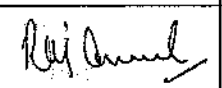
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_013

SOP Title: Drug recalls

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome – Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Dec-2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 – reviewed to ensure information still current	
3	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

- Provide guidance on the actions to take to prevent drug or investigational medicinal product (IMP) being used when notification is received that it is defective or the clinical trial of an IMP has been stopped suddenly.

2. DEFINITIONS

- Drug recall – procedure to identify, locate, retrieve and stop the use of drug or IMP which has been identified as unsuitable for use.

3. PROCEDURE and RESPONSIBILITIES

3.1. Licensed medicines

3.1.1. The Trust medicines policy SH CP 1 (Medicines, Control, Administration and Prescribing Policy, MCAPP) deals with drug recalls and alerts relating to defective licensed medicines. See MCAPP.

3.1.2. Write on the Drug Alert/ Safety Notice the details of the trials affected by the alert. File one copy of the Drug Alert/ Safety notice in the relevant clinical trial's main pharmacy site file.

3.1.3. Inform the Investigator(s) and study co-ordinator.

3.2. IMPs

3.2.1. Information on problems relating to IMPs will be received from the sponsor or the monitor working on the sponsor's behalf. The sponsor or monitor will issue guidance on the actions to take.

3.2.2. All sponsor guidance must be filed in the relevant clinical trial's main pharmacy site file.

3.2.3. Inform the Investigator(s) and study co-ordinator if not already done so.

3.3. Unused defective IMPs

3.3.1. If the research team or pharmacy staff are notified that a batch of IMP is defective and

unsuitable for use then the affected unused IMP must be quarantined and action taken to prevent it being used. See SOP CP/R&D_012 Quarantining of Investigational Medicinal Products.

3.4. Defective IMP issued to patients

3.4.1. If the defective IMP has already been dispensed to patients but has been declared unsuitable for use, patients must be contacted urgently by the principal investigator, study co-ordinator or research nurses to stop them taking any more doses of the defective IMP. Make arrangements to collect the IMP from them. Depending on the availability of IMP that is suitable for use, new treatment kits may be issued to replace the defective IMP. The sponsor will issue guidance on the actions to take.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensure a drug recall procedure is in place
2	Clinical trials pharmacist	Staff receiving drug recall or alert	Staff receiving notification of a drug recall or alert are responsible for ensuring that the recall procedure is followed.
3	Principal Investigator	Study co-ordinator, research nurses	Contacting patients
4	Clinical trials pharmacist	Clinical trials pharmacist, clinical trials technician	Confirm that all patients have been notified of need to stop drug, all defective drug has been returned and new supply has been issued where appropriate.

4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 1 Medicines Control, Administration and Prescribing Policy
- CP/R&D_012 Quarantining of Investigational Medicinal Products

5. TRAINING

- ICH-GCP guidelines
- Awareness of MHRA drug recall procedures

6. REFERENCES