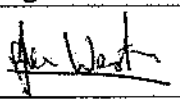
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_010

SOP Title: Staff training in medicines management for clinical trials

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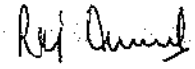
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	November 2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 - Template updated to ensure SOP matches current practice and make reference to dispensing workshop training	
3	1-June-2018	Reviewed to ensure that content is current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) identifies the training needs of staff participating in the medicines management of Investigational Medicinal Products (IMPs)

2. DEFINITIONS

- Medicines Management- this term covers all activities relating to IMPs

3. PROCEDURE and RESPONSIBILITIES

3.1 Training requirements

3.1.1 All staff working within the Trust, who are involved in any way with the use of medicines, must familiarise themselves with the appropriate sections of the Medicines Control, Administration and Prescribing Policy (MCAPP), SH CP 1

3.1.2 Before undertaking activities involving IMPs staff must undergo training for that activity. Training is required to undertake the following activities:

- Ordering of drug
- Receipt and recording of delivery of drug
- Storage
- Code breaking
- Supply of drug, including prescribing and dispensing
- Reconciliation of drug
- Disposal of patient returns and unused drug
- Maintaining a pharmacy study file
- Archiving

3.1.3 Staff undertaking any of these activities must ensure that they are on the delegation log to do so for the trial in question.

3.1.4 Training is available as part of the site initiation visit and from the clinical trials pharmacist or clinical trials pharmacy technician.

3.1.5 A record of training will be kept to show that training has occurred and the trainee understands the activity, their roles and responsibilities

3.2 Specific dispensing training

3.2.1 All non-pharmacy staff must undergo regular revalidation of their dispensing skills. This is not expected to be greater than every two years.

3.2.2 All non-pharmacy staff that dispense a clinical trial must be signed off as being competent to do so by the clinical trials pharmacist. Competency is assessed either using a workshop training package, or through dispensing logs that must be checked by an approved final checker (see section 3.3).

3.2.3 Any member of staff may be prohibited from undertaking any dispensing activity if, in the opinion of the clinical trials pharmacist, it is in the interest of patient safety to do so.

3.2.4 A member of staff who is deemed competent to dispense may dispense any trial as long as they are on the delegation log to do so. A list of staff competent to dispense is maintained by the clinical trials pharmacist.

3.2.5 As per the Trust's Medicines Policy (SH CP 01), doctors are not permitted to dispense trial medication.

3.3 Specific final accuracy checking training

3.3.1 All research nurses must undergo regular revalidation of their checking skills. This is not expected to be greater than every two years.

3.3.2 All nurses who final accuracy check a clinical trial must be signed off as being competent to do so by the clinical trials pharmacist. Competency is assessed using a final checking log that must be checked by an approved checker.

3.3.3 Any member of staff may be prohibited from undertaking any final accuracy checking activity if, in the opinion of the clinical trials pharmacist, it is in the interest of patient safety to do so.

3.3.4 Only research nurses and pharmacy staff are permitted to act as a final checker. A research nurse who has demonstrated competence to final accuracy check may do so on any trial as long as they are on the delegation log to do so. A list of staff competent to act as final accuracy checkers is maintained by the clinical trials pharmacist.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensures that processes are in place for staff to receive training
2	Clinical trials pharmacist	Clinical trials pharmacist and clinical trials technician	Delivery of pharmacy training to non-pharmacy staff
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 1 Medicines Control, Administration and Prescribing Policy
- CP/R&D_007 Dispensing of clinical trial medication
- CP/R&D_019 Accuracy checking of clinical trial medication

5. TRAINING

- ICH-GCP training
- An understanding of dispensing procedures.
- An understanding of the protocol procedures
- An understanding of final accuracy checking procedures (if needed for role)

6. REFERENCES