York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S49

Training of Pharmacy Personnel

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and R&D Newsletter for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html

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	Date:	22nd December 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	22nd December 2015

This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	27th February 2012	
2.0	24th October 2013	Removal of references to the North and East Yorkshire R&D Alliance
3.0	19th January 2016	Updated references to the new Pharmacy clinical trials guidance published in October 2013. Removed requirement for Pharmacist trials training every 2 years. Removed references for publishing trial instruction on Q pulse. Removed references to Pharm/T25. Removed references to labels unlimited software.

Contents

1 Introduction, Background and Purpose

Part 2 (2) of Schedule 1 to Statutory Instrument 2004/1031 requires that 'Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.'

Consequently, Pharmacy staff within York Teaching Hospital NHS Foundation Trust, who are part of providing the Pharmacy service to clinical trials must be 'adequately qualified, trained and experienced to assume clinical research responsibilities' as stated in the Professional Guidance on Pharmacy Services for Clinical Trials produced by the National Pharmacy Clinical Trials Advisory Group.

The purpose of this SOP is to ensure that the following are achieved and documented accordingly;

1. Any member of the Pharmacy clinical trials team who is involved in dispensing Investigational Medicinal Product (IMP) as part of a clinical trial (or any other role assigned on the delegation log for a trial e.g. drug accountability) is adequately qualified, trained and competent to fulfil this role.

2. Any Pharmacist who is involved in checking clinical trials prescriptions is adequately trained and competent to fulfil this role.

3. All staff within the clinical trials team have up to date training records, GCP certificates and CV's available.
4. All staff within the clinical trials team receive study-specific training prior to dispensing of any IMP as part of the trial.
5. Signature logs are maintained for any Pharmacy staff involved in clinical trial activity.

2 Who Should Use This SOP

This procedure applies to all staff working within the Pharmacy clinical trials team at York and Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used when training Pharmacists, Pharmacy Clinical Trials Managers, Senior Pharmacy Technicians and Senior Assistant Technical Officers in procedures relating to clinical trials dispensing or checking. This SOP should be used when maintaining accurate records of training for individuals with responsibilities towards clinical trials within Pharmacy at York Teaching Hospitals NHS Foundation Trust.

4 Procedure(s)

4.1 Training and education requirements of members of the Pharmacy clinical trials team

All members of the Pharmacy clinical trials team must be qualified by education, training and experience to fulfil their role within the trial. A list of the generic job specifications for all grades of staff is available on the Pharmacy X drive and each person specification will indicate the requirements for the role.

All Pharmacists involved in clinical trials must have a Masters Degree in Pharmacy (or equivalent) and be registered with the General Pharmaceutical Council.

The Pharmacy Clinical Trials Manager must have completed a First degree in Pharmacy (Masters), or in another relevant Health Sciences subject.

A Senior Pharmacy Technician must have completed a BTEC in Pharmaceutical Science or NVQ Level 3 in Pharmacy Services or equivalent, and must be registered with the General Pharmaceutical Council.

A Senior Assistant Technical Officer must have obtained a QCF level 2 qualification in Pharmacy Services or equivalent, and must also have GCSEs or equivalent in Maths and English Grades A-C, alongside a basic knowledge and understanding of health and safety.

4.2 Clinical trials dispensing training for Senior Pharmacy Technicians and Senior Assistant Technical Officers

Any member of the Pharmacy clinical trials team who is involved in dispensing IMP as part of a clinical trial (or any other role assigned on the delegation log for a trial e.g. drug accountability) must be adequately qualified, trained and competent to fulfil this role.

Until they have completed their training in clinical trials, any member of the Pharmacy clinical trials team who is involved in dispensing or handling IMP as part of a clinical trial must work under the direct supervision of a competent Senior Pharmacy Technician or the Pharmacy Clinical Trials Manager.

To become competent in dispensing IMP as part of a clinical trial, the relevant member of staff must complete the following;

- York Hospital Pharmacy department training programme – clinical trials dispensing training pack (See Appendix 1 for details of what constitutes this training).

- Good Clinical Practice (GCP) training.

- Validation of their clinical trial dispensing.

- Read the Pharmacy clinical trial Standard Operating Procedures

A Senior Pharmacy Technician or the Pharmacy Clinical Trials Manager will train the relevant member of staff using the training pack in Appendix 1, assess their competence while working through the training pack and will subsequently sign their training pack as evidence that they have successfully completed their training.

A copy of the completed training pack for each member of staff trained in clinical trials dispensing should be scanned and saved into the staff's personal training file in X:\Clinical Trials\Admin

New members of the Pharmacy clinical trials team should also receive study-specific training prior to dispensing the trial alone. This may involve shadowing a trained and competent member of staff, and then dispensing the trial alone with a check by a member of the Pharmacy clinical trials team prior to a check by the Pharmacist. The training requirements for the individual should be discussed when the member of staff joins the team, and a form should be created to document any training provided.

Validation of the training of a new member of the clinical trials team will be assessed through completion of a 50 item dispensing log.

See section 4.2.1 for more details and how the re-validation process is conducted.

See Section 4.3 for details of GCP training required.

The latest versions of the Pharmacy clinical trials standard operating procedures are available on the York Foundation Trust Research and Development Unit website (www.northyorksresearch.nhs.uk). As described in Pharm/S60 (Publishing Clinical Trial Standard Operating Procedures on Q-Pulse), when a new clinical trial SOP or associated form is published, the Pharmacy Clinical Trials Manager or Senior Pharmacy Technician should forward the SOP to the Pharmacy Quality Assurance team, with a request for the document to be published on Q-Pulse. Upon receipt of an email from Q-Pulse alerting that a new SOP or form has been distributed, recipients should read and acknowledge the document to confirm they have read and understood the document. This should be done prior to the formal implementation date where possible.

The Pharmacy Clinical Trials Manager should ensure that staff are notified of any new or amended SOPs and carry out training prior to implementation.

4.2.1 Revalidation of Senior Pharmacy Technicians and Senior Assistant Technical Officers in clinical trials dispensing

Any member of the Pharmacy Clinical Trials team who is involved in dispensing IMP as part of a clinical trial will be revalidated every 12 months to ensure they are still competent in dispensing clinical trials. The validation will consist of completion of a 50 item dispensing log for clinical trial prescriptions without a major error (1 minor error is allowed) (see Appendix B). If a major error is identified or more than one minor error is made the individual will be subject to further observation and assessment of competency using the original training pack and will have to complete the 50 item log again.

It is the responsibility of the Pharmacy Clinical Trials Manager to ensure this revalidation is completed every 12 months and documented as such. The 'York Hospital Pharmacy department training programme – Clinical trials dispensing training pack' should be signed and dated (on the final page) by the Pharmacy Clinical Trials Manager as evidence of this revalidation.

Any member of the Pharmacy clinical trials team who is involved in dispensing IMP as part of a clinical trial is also required to read the clinical trial summary and dispensing procedure that is present within the trial instructions of each pharmacy clinical trial file and sign the Pharmacy signature log (present in every clinical trial file) or other relevant training log prior to dispensing a clinical trial prescription. In this way they agree to follow the procedure that is in place for the study.

The dispensing procedure should be followed at each dispensing episode as the procedure may have been amended, and a new version implemented. If a new version of the procedure is in place, the Pharmacy signature log for this version should be signed as evidence that the correct version of the procedure is being followed.

4.3 Pharmacist training in clinical trials

Any Pharmacist who is involved in checking IMP dispensed as part of a clinical trial must be adequately qualified and trained to fulfil this role.

Any Pharmacist that is involved in checking a clinical trials prescription in the dispensary as part of a clinical trial is required to read the Clinical trial summary and Pharmacist checking procedure that is present within each Pharmacy clinical trial file.

They should sign the Pharmacy signature log (present in every clinical trial file) prior to checking the clinical trial prescription. In this way they agree to follow the procedure that is in place for the study. The checking procedure should be followed at each dispensing episode as the procedure may have been amended and a new version implemented. If a new version of the procedure is in place, the Pharmacy signature log for this version should be signed as evidence that the correct version of the procedure is being followed. An accuracy checking checklist may be in use for the trial.

If so, the Pharmacist should follow this checklist and sign & date to confirm this. See Pharm/S90 for more details.

4.4 GCP Training

Any Senior Pharmacy Technician, Senior Assistant Technical Officer, Pharmacy Clinical Trials Manager or Pharmacist who is a member of the Clinical trials team (or any other staff who are trained in dispensing clinical trials) and are delegated responsibilities as part of a clinical trial (as recorded on the delegation log), must complete training in Good Clinical Practice (GCP). This must be completed at least once every 2 years.

Once completed, a copy of the relevant GCP training certificate must be placed in the file in the clinical trials office (named CV's and GCP certificates) as evidence of this. These can be provided to Trial Sponsors upon request. GCP certificates may not be filed in the individual Pharmacy trial files, in accordance with the Pharmacy Clinical Trial File Contents SOP (Pharm/F52), and may be referenced as being stored centrally through an appropriate file note.

Any Directorate Pharmacists that are delegated responsibilities as part of a clinical trial and therefore appear on the delegation log for the trial must also complete GCP training as described above.

4.5 Trial specific Instructions/dispensing and checking procedures training

Every member of the Pharmacy clinical trials team must receive training in the Pharmacy Trial Instructions (or procedures relating to handling of the IMP in Pharmacy, including the dispensing instructions) prior to Pharmacy readiness being issued to the R&D department and subsequent commencement of the trial (See Pharm/S41) where possible. At a minimum, this training will consist of communication of the Pharmacy Trial Instructions relating to that trial. The training given and details of who has received it should be recorded on Pharm/F61 (Pharmacy Training Record) and a copy of this kept within the relevant Pharmacy clinical trial file.

4.6 Curriculum Vitae

Every member of the Pharmacy clinical trials team must be able to demonstrate their training and experience to carry out their role as part of the Pharmacy Clinical Trials team through their Curriculum Vitae (CV).

Once completed, a copy of the relevant CV for every member of the clinical trials team must be placed in the file in the clinical trials office

(named CV's and GCP certificates). These can be provided to Trial Sponsors upon request. CV's may not be filed in the individual Pharmacy trial files, in accordance with the Pharmacy Clinical Trial File Contents SOP (Pharm/F52), and may be referenced as being stored centrally through an appropriate file note.

It is the responsibility of each member of the Pharmacy clinical trials team to maintain their own CV following any training courses attended or review of their relevant experience. This should be done on an annual basis as a minimum.

It is the responsibility of the Senior Assistant Technical Officer to maintain the folder named 'CV's and GCP certificates' on behalf of the Pharmacy clinical trials team.

4.7 Tracking of Training

Records of the following dates for all relevant individuals (Pharmacists and members of the Pharmacy clinical trials team) will be tracked on a spreadsheet for the purpose of ensuring compliance with the mandated timescales for completion;

- Completion of initial clinical trials dispensing training
- Completion of annual revalidation
- Completion of initial and subsequent GCP training every 2 years
- Production of an amended CV on a yearly basis

This will be the responsibility of the Senior Assistant Technical Officer in clinical trials. This should be reviewed on a regular basis.

This will be stored on the Pharmacy X drive under the heading X:\Clinical Trials\admin\clinical trials training.

5 Related SOPs and Documents

Professional Guidance on Pharmacy Service to Clinical Trials, National Pharmacy Clinical Trials Advisory Group, Version 1, October 2013.

Good Clinical Practice Guide (The Grey Guide), 2012

Pharm/S41 – Pharmacy Trial Assessment and Confirmation of Readiness

Pharm/F52 - Pharmacy Clinical Trials File Contents

Pharm/S90 – Accuracy checking of clinical trial prescriptions

Pharm/F61 – Pharmacy Training Record

Pharm/S60 – Publishing Clinical Trial Standard Operating Procedures

on Q-Pulse

6 Appendix A - Clinical trials training pack

7 Appendix B – Annual Clinical Trials Dispensing Revalidation Programme

York Teaching Hospital NHS Foundation Trust

YORK HOSPITAL PHARMACY DEPARTMENT TRAINING PROGRAMME

Clinical trials dispensing

TYPES OF EVIDENCE	METHOD
Underpinning knowledge	✓ Read S.O.P. ✓ Read dispensing procedures ✓ One to one training session
Observations	✓ Trainer ✓ Mentor ✓ Trials Technician/Manager/Pharmacist
Testing of knowledge and understanding	✓ Oral questions
Assessment of competency	✓ Observation by Trials Technician/ trainer on 3 separate occasions
Revalidation	✓ Complete revalidation log every 12 months

CHECKLIST for Clinical trials dispensing

ALL ITEMS ON THE CHECKLIST MUST BE EXPLAINED BY TRAINER

Read Clinical Trials terms	☐
Read NIHR 'Understanding Clinical trials' booklet	☐
Read Professional Guidance on Pharmacy Services to clinical trials (NPCTAG)	☐
Understand how clinical trials are set up, file contents and use of the Pharmacy checklist	☐
Sign appropriate Pharmacy signature logs and request appropriate IWRS access (if applicable)	☐
Overview of current clinical trials	☐
Awareness of new clinical trials and pending studies	☐
Check Clinical trial prescription for essential details	☐
Locate correct trial file / supplies – Trial status Inventory list	☐
Locate and read dispensing procedure in front of file	☐
Check correct trial patient number and verify correct patient	☐
Supply correct trial drugs and sufficient quantities / IVRS kit numbers	☐
Tear off labels	☐
Additional authorised labels to complete & Label Accountability form	☐
Labels on Bottles/kits	☐
Sign Prescription / For Pharmacy use section	☐
Complete all dispensing documentation in file / Master Drug accountability logs/Individual patient accountability logs	☐
Ensure prescription checked and file prescription	☐
Handing trial medications to Nurses or patients and counselling	☐
Trial Returns	☐

Candidate Signature: …… Date: ……..

Trainer Signature: …… Date: ……..

CHECKLIST for Clinical trials dispensing

ALL ITEMS ON THE CHECKLIST MUST BE EXPLAINED BY TRAINER

Complete all returns documentation in trial file	☐
Trial Returns storage	☐
Temperature monitoring – daily and weekly monitoring	☐
Temperature excursions and quarantine procedures	☐
Dealing with Trial Monitors and Clinical Research Associates (CRA's) – correspondence, Initiation and monitoring visits	☐
Understanding the closedown of a trial and what happens when they finish	☐
Randomisation of patients and Code breaking procedures	☐
Deal with queries on prescriptions	☐
Deal with queries from patients/Nurses/Drug company	☐
Know who and when to refer queries to	☐
Complete Trial Quiz	☐
Complete Individual Patient drug accountability record	☐
Understand the roles of the Research Nurse, R&D Manager and Clinical trials Team	☐
Meet with a Research Nurse and R&D Manager	☐
Read all Pharmacy clinical trials SOP's (www.northyorksresearch.nhs.uk)	☐
Understand Trials approvals (MHRA, Ethics, NHS permission)	☐
Attend Good Clinical Practice training day & do NIHR online Pharmacy IMP management course	☐
Dispensing oral chemotherapy from Chemocare prescriptions	☐
Order and Receipt of IMP including quality checks (QP release)	☐
Labelling requirements, systems and production of IMP labels and associated documentation – Read Annex 13 of GMP	☐
Destruction of used and expired IMP and associated documentation	☐

Candidate Signature: …… Date: ……

Trainer Signature: …… Date: ……

OBSERVATION CHECKLIST

A minimum of **2 separate** observations must be achieved.

TASK	Observed by	Level of Achievement	Date	Observed by	Level of Achievement	Date	Observed by	Level of Achievement	Date
Attend Initial induction									
Attend Background knowledge session									
Complete specimen signatures when dispensing									
Check trial prescription is completed accurately									
Locate correct trial file									
Read dispensing procedures									
Check for correct trial patient number									
Supply correct trial drugs									
Supply sufficient quantities									
Take correct actions with tear off labels									
Add additional labels & do label accountability									
Complete label on container									
Sign prescription/complete pharmacy section									
Complete all dispensing logs in the file									
Ensure prescription is checked									
File prescription and associated documents									
Hand trial drugs to nurse or patient									
Counsel patient if appropriate									
Receive clinical trials returns									
Assess clinical trials returns									
Complete trial return logs in file									

1 = achieved required standard 2=NOT achieved required standard

OBSERVATION CHECKLIST cont'

A minimum of **2 separate** observations must be achieved.

TASK	Observed by	Level of Achievement	Date	Observed by	Level of Achievement	Date	Observed by	Level of Achievement	Date
Package returns for storage									
Temperature monitoring									
Deal with clinical trials monitors									
Deal with problems with a trials prescription									
Answer queries about clinical trials									
Awareness of trial code breaks									
Complete trial quiz									
Complete Individual trial dispensing log									
Destroy IMP and complete certificate of destruction									
Receive an IMP and complete accountability log									
Order an IMP and file relevant documentation									
Use of IVRS/IWRS systems									
Tracking patient prescriptions in diary									
Use quarantine logs and associated documents									
Use Pharmacy checklist									
Produce IMP labels & complete label accountability									

1 = achieved required standard 2=NOT achieved required standard

CLINICAL TRIALS DISPENSING

The following criteria must be completed and signed off by the relevant trainer.

CRITERIA	Signature of Trainer	Date
UNDERPINNING KNOWLEDGE		
OBSERVATIONS		
TESTING OF KNOWLEDGE AND UNDERSTANDING		
SIMULATION		
ASSESSMENT OF COMPETENCY		
ANNUAL VALIDATION		

Oral questions asked:

1. What is a Clinical trial?
2. Why are there strict accountability logs to be completed?
3. What do the following terms mean:- ‘double blind’, ‘CRA’, ‘Double dummy’?
4. When would you ‘break a code’ on a clinical trial?
5. What would you do if you received a prescription with the wrong protocol number on?
6. What is a delegation log and why is it important when dispensing?
7. What happens when a clinical trial finishes?
8. Where do you find the latest versions of the Pharmacy clinical trials SOP’s?
9. Describe the process of receiving an IMP in Pharmacy? What are the important Quality checks?

I …….. confirm that …….. is competent to …….

……..
Candidate Signature: ……... Date: …….
Trainers Signature: ……... Review Date: …….

CLINICAL TRIALS DISPENSING

To be completed by the Trainer.

Candidates name: ……

I ……confirm that ……..is competent to deal with clinical trial dispensing at York hospital.

Candidate signature: ……..Date: ……

Trainers signature: ……..Date: ……

Review date: ……

Validation (every 12 months)

Date and sign when validation (Clinical trials dispensing log) is completed

Date: …… Signature: ……..

Date: …… Signature: ……..

Date: …… Signature: ……..

Date: …… Signature: ……..

Date: …… Signature: ……..

Date: …… Signature: ……..

Date: …… Signature: ……..

Pharmacy Department

Annual Clinical Trials Dispensing Revalidation Programme

for

Pharmacy Technicians and support staff

Name……

Clinical trial Dispensing Revalidation Exercise

Complete a rolling **50 ITEM** DISPENSING ACCURACY LOG covering a range of trials.

Trial Name	1. Labelling error codes	2. Assembling error codes	3. Documentation error codes
Complete name of trial you are dispensing on the log	1. Drug name*	10. Drug *	20. Prescriber not on delegation log*
	2. Drug form*	11. Drug form*	21. Patient specific accountability log incomplete*
	3. Drug strength*	13. Drug strength*	22. Master Accountability log incomplete*
	4. Quantity*	14. Quantity*	23. Prescription incomplete*
	5. Patients name*	15. Expired*	24. Tear off label not attached*
	6. Directions*	16. Incorrect container*	25. Other – please indicate
	7. Missing warnings*	17. Missing Item*	
	8. Cost centre	18. Missing signature	
	09. Bag label	19. Missing additions e.g. steroid card	

6.1.1.1.1 * **Major error**

Definition – likely to result in potential harm to the patient

6.1.1.1.2 Minor error

Definition – those likely to cause inconvenience to patient, carer or pharmacy

No more than 1 minor error will be allowed – No major errors are allowed

IMPORTANT

Upon completion, scan and save a copy in your personal training file on the X drive (York).

Name……..

Date	Prescription Type	Final Checker	Error Code

Name……..

Date	Prescription Type	Final Checker	Error Code

Name……..

Date	Prescription Type	Final Checker	Error Code

Name……

Date	Prescription Type	Final Checker	Error Code

Name……..

Date	Prescription Type	Final Checker	Error Code