York Foundation Trust R&D Unit
SOP
Pharm/S87

Recording and monitoring of dispensing errors in clinical trials.

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	28th July 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	28th July 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	20th August 2015	

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1 Introduction, Background and Purpose

It is essential that the Pharmacy clinical trials service has a process for recording dispensing errors to ensure lessons are learnt from mistakes. Therefore the purpose of this SOP is to ensure all dispensing errors are recorded and monitored so corrective action can be taken.

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 staff have made a dispensing error.

4 Procedure(s)

If a dispensing error is detected the person who detects the error must:

1. Collect the dispensing error monitoring file kept in the clinical trials room (this file contains Pharm/F29 – Dispensing Error Reporting Log & Pharm/F30 – Dispensing Error Reporting Codes)
2. On the next free line of the Dispensing Error Reporting Log (Pharm/F29) complete the following sections as appropriate:

- Reference number – Create this number from the date and the next consecutive number i.e. ddmmyy followed by the number. If it is the first recorded error for that day the last 2 digits will be 01, the next error recorded will be ddmmyy02 etc.
- Time
- Prescription Type (Refer to Pharm/F30)
- Error Code (Refer to Pharm/F30)
- Escaped (Yes/No)
- Name of trial
- Details of error
- Dispenser's full name
- Checker's full name

3. If supplying an incorrect label as additional evidence of error - attach the label to the reverse of the error monitoring form. Next to the label, document the error reference number (as defined in step 2).
4. Identify the member of staff who has made the error and provide them with appropriate feedback - acknowledge whether or not this has been completed by stating 'Yes' or 'No' in the appropriate column. Where possible feedback should always be given immediately after an error has been detected. If you are unable to give feedback this must be documented.

5. If feedback has been given, obtain the signature from the member of staff making the error as evidence that they have received the feedback. They should sign in the 'Feedback Received' column.
6. All dispensing errors must immediately be reported to the Clinical Trials Manager or Clinical Trials Pharmacist so it can be assessed if it constitutes a serious breach of Good Clinical Practice or study protocol (refer to R&D/S04 - Serious Breach of GCP or the Study Protocol).
7. All dispensing errors must be reviewed by the pharmacy clinical trials team every month and appropriate action taken to try and prevent them happening again.

5 Related SOPs and Documents

Pharm/F29 – Dispensing Error Reporting Log
Pharm/F30 – Dispensing Error Reporting Codes
R&D/S04 – Serious Breach of GCP or the Study Protocol
Pharm/S104 – Clinical Trials Deviation Reporting SOP
Pharm/F107 - Clinical Trials Deviation Reporting Form