York Foundation Trust R&D Unit
SOP
Pharm/S104

Documenting, managing and reporting deviations.

(to be used in conjunction with Pharm/F107 – Deviation Assessment Form)

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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Author:	Mark Elliott
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Approved by:	Name/Position:	Jax Westmoreland - Principal Pharmacist for Clinical Trials and Research
	Signature:	Signed copy held by R&D Unit
	Date:	25th November 2015
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	25th November 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	23rd December 2015	-

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1 Introduction, Background and Purpose

The purpose of this SOP is to ensure that the Pharmacy clinical trials team act upon and record any planned or unplanned deviations appropriately. It is important we follow the process described in this SOP to ensure a quality service is delivered and corrective action is taken so patient safety is ensured. Examples of deviations include temperature excursions, unapproved changes to documents or equipment, and divergence from trial protocols or SOPs.

If a deviation is classed as a serious breach of protocol or Good Clinical Practice (GCP) you must report this according to R&D/S04 – Serious breach of GCP or the study protocol. The definition of a 'serious breach' is 'A routine or systematic deviation from the protocol which is likely to affect to a significant degree: the safety or physical or mental integrity of the subject of the trial or the scientific value of the trial' (Medicines for Human Use Clinical Trial Regulations 2004)'.

If a deviation does not result in harm to the study subject(s) or significantly affect the scientific value of the reported results of the study this must be documented but it will not be classed as a serious breach.

Please note that quality exceptions (deviations) occurring in the Aseptic Unit will need to be processed according to the Aseptic SOPASEP04 – Quality Exception Reporting.

2 Who Should Use This SOP

This SOP should be followed by all trained members of the pharmacy clinical trials team within the pharmacy departments 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 planned or unplanned deviations occur.

4 Procedure(s)

1. All deviations must be reported immediately to the most senior member of the clinical trials team on duty (NB. For temperature excursions also refer to Pharm S48 and for dispensing errors also refer to Pharm S87).
2. Where there is a requirement to take immediate corrective action to ensure patient safety, verbal agreement of action must be sought from a Pharmacist to ensure timely and appropriate measures are implemented, and Pharm/F107 can be completed retrospectively.

3. All deviations of GCP or protocol must be clearly and systematically documented, in order for appropriate corrective and preventive actions to be taken so please complete Pharm/F107 as per below:
   - Name of person completing form.
   - Signature of person completing form.
   - Date deviation identified.
   - Date form completed.
   - Full details of the deviation (give a clear description).
   - Location/s at which the deviation occurred.
   - Names of personnel involved.
   - Batch number/s of product/s affected & file note/s (if appropriate).
   - Study title/s affected.
   - Action/s taken.
   - An assessment should be made by the Clinical Trials Manager (or designated individual) as to whether the breach is serious or not. If necessary advice should be sought by contacting the R&D Unit (refer to R&D/S04). Once concluded tick Yes or No then add signature, date and time.
   - Reference number is consecutive (e.g. Y0001, Y0002 etc).
4. Ensure all corrective and preventative actions are taken (as appropriate).
5. All suspected serious breaches must be reported:
   - For Trust sponsored and co-sponsored studies these must be reported to the R&D Unit within 24 hours of the breach being identified.
   - For studies hosted by the Trust these must be notified directly to the study sponsor, and at the same time, the Head of R&D (or delegate) must also be notified if a suspected serious breach has occurred within the Trust (refer to R&D/S04).
6. If the deviation involves a process external to Pharmacy clinical trials (e.g. Aseptic Unit, Pharmacy Stores and Distribution, Satellite Unit) then staff may process this according to their own SOP's and forms. If appropriate, Pharmacy clinical trial staff should obtain a copy of any relevant documentation and attach to our Deviation Assessment Form.
7. File Pharm/F107 in the Deviation Assessment Form file (NB. Each site will maintain a file).
8. The Pharmacy Clinical Manager (or designated individual) must review individual deviations, in a timely manner, taking a risk based approach to ensure they are closed (i.e. all corrective and preventative actions have been implemented).
9. The Pharmacy Clinical Manager (or designated individual) must review ALL deviations each month to understand trends; if a pattern of repetition of non-serious breaches is noted, this may amount to a quality control failure and become serious and therefore reportable.
10. Feedback must be given to individuals and department/s as appropriate.
11. File notes must still be completed (if appropriate) for any relevant trial/s and this should reference the Deviation Report Form.
12. All deviations may be recorded/tracked on a spread-sheet or database to help identify trends and inform appropriate corrective action.

5 Related SOPs and Documents

Pharm/F107 - Deviation Assessment Form

R&D/S04 – Serious breach of GCP or the study protocol

SOPASEP04 – Quality Exception Reporting

R&D/T20 – File Note Template

R&D/F59 – File Note Log

Pharm S87- Recording and monitoring of dispensing errors in clinical trials

Medicines for Human Use Clinical Trial Regulations 2004