York Foundation Trust R&D Unit SOP Pharm/S60



Publishing Clinical Trial Standard Operating Procedures on Q-Pulse

IT IS THE RESPONSIBILITY OF <u>ALL</u> 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference: Pharm/S60

Version Number: 2.0

Author: Richard Evans Implementation date of current version: 20th July 2015

Approved by: Name/Position: Jax Westmoreland, Principal Pharmacist,

Clinical Trials and Research

Signature: Signed copy held by R&D Unit

Date: 16th June 2015

Name/Position: Sarah Sheath, SOP Controller

Signature: Signed copy held by R&D Unit

Date: 16th June 2015

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

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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	12 th July 2013	Removal of section 4.2 detailing the distribution of trial instructions to Pharmacists through Q-pulse.
2.0	20 th July 2015	

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1 Introduction, Background and Purpose

Q-Pulse is an electronic software application used by York Teaching Hospital NHS Foundation Trust to ensure that standard operating procedures (SOPs) are available to all appropriate members of staff within pharmacy. It ensures SOPs are accessible, and can be acknowledged as having been read and understood by those who read them.

Clinical Trial SOPs written by members of the Pharmacy clinical trials team in the Pharmacy department at York Teaching Hospital NHS Foundation Trust are authorised by the Principal Pharmacist, Clinical Trials and Research and the R&D unit SOP Controller, before being published on the York Foundation Trust R&D website, http://www.northyorksresearch.nhs.uk/. By adding newly authorised Pharmacy Clinical Trial SOPs for distribution through Q-Pulse, a record can be maintained of staff members who have read and acknowledged these SOPs. This should also give access to the most recent version.

2 Who Should Use This SOP

This procedure should be followed by all members of the clinical trials team within the pharmacy department at York and Scarborough hospitals, who form part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used to ensure that all pharmacy clinical trial SOPs and associated forms published on the York Teaching Hospital NHS Foundation Trust R&D website (http://www.northyorksresearch.nhs.uk/) are added to the Q-Pulse distribution system.

Q-Pulse can be used to generate a list of the SOPs and versions which have been acknowledged by relevant pharmacy staff. This list may be used to update personal training files or to prepare for an audit or MHRA inspection. When required, this list can be provided by the Principal Pharmacy Technician or Senior Pharmacy Technician in Quality Assurance.

4 Procedure(s)

- 1. When a new SOP has been published by the SOP Controller in the R&D unit, an email will be sent to the members of staff who are required to read it approximately one month prior to its formal implementation.
- 2. Upon receipt of a 'Research SOP update alert' email from the R&D department which involves a pharmacy clinical trials SOP or associated form, the Pharmacy Clinical Trials Manager or Senior Pharmacy Technician should forward this email to the Principal Pharmacy Technician or Senior Pharmacy Technician in Quality Assurance, with a request for this document to be published on Q-Pulse. This will allow members of the pharmacy clinical trials

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team and other relevant staff at York and Scarborough hospitals to read and acknowledge.

3. 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.

5 Related SOPs and Documents

York Teaching Hospital NHS Foundation Trust R&D website (http://www.northyorksresearch.nhs.uk/)

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