

Self-directed training in York Foundation Trust R&D Unit Standard Operating Procedures on Q-Pulse

**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 or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	R&D/S22
Version Number:	2.0
Author:	Monica Haritakis
Implementation date of current version:	15 th June 2017

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	18 th May 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	18 th May 2017

This SOP will normally be reviewed every 3 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	25 th April 2016	
2.0	15 th June 2017	Minor changes made for clarification.

UNCONTROLLED DOCUMENT WHEN PRINTED

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	1
4 Procedure(s)	1
5 Related SOPs and Documents	2

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 the R&D Unit and across all clinical research specialities. It ensures SOPs are accessible, and can be acknowledged as having been read and understood by the recipients.

York Foundation Trust R&D Unit SOPs are approved by the Head of R&D 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 SOPs for distribution through Q-Pulse, a record can be maintained of staff members who have read and acknowledged the distributed documents. This also ensures access to the most recent version of written procedures.

2 Who Should Use This SOP

This procedure should be followed by all members of clinical research teams & R&D Unit staff within York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used to ensure that all York Foundation Trust R&D Unit SOPs and associated forms/templates/guidance 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, and made available to staff for their self-directed training.

4 Procedure(s)

Q-Pulse can be used to generate a list of the SOPs and versions which have been acknowledged by relevant research 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 R&D Unit SOP Controller or Research Quality Assurance (QA) staff.

When a new SOP or an updated version of an SOP has been published by the SOP Controller on the R&D Unit website, at the same time this document will be published on Q-Pulse and distributed to all research teams and R&D staff approximately one month prior to its formal implementation date. This will allow the recipients to read and acknowledge all the distributed documents..

Appropriate self-directed training must be performed by all staff involved in the conduct of clinical research. The extent of this training will depend on the activities undertaken by particular members of staff and should be specific to their roles and responsibilities.

Upon receipt of an email from Q-Pulse alerting that a new SOP or an updated version of an SOP or other document has been distributed, recipients should

read the document, assess its relevance to their role and responsibilities, and acknowledge confirming they have read and understood it. This should be done prior to the formal implementation date where possible.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach the SOP Controller who will arrange additional training.

All staff are responsible for maintaining their own training records and copies must be made available to the SOP Controller or study monitors on request.

All new members of staff should be directed to the R&D Unit SOP Controller or Research Quality Assurance staff to be issued with Q-Pulse training and access to the system.

5 SOPs and Documents

R&D/S25 Providing and Documenting Training for Researchers

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