York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S01

Preparation, Review and Approval of Standard Operating Procedures for Research

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/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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S01
Version Number:	11.0
Author:	Deborah Phillips
Implementation date of current version:	18th July 2019

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	20th June 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	20th June 2019

This SOP will normally be reviewed at least 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	8th December 2005	Original SOP
2.0	24th September 2007	Minor typos corrected. Version history log inserted.
3.0	1st August 2009	Many revisions. Preparation and review procedure clarified. Flow diagram added. Updated Alliance name. Added watermark. Added training section. Added reference texts. Change to SOP reference numbering. Change to front page signature/authorisation box. SOP Archiving added.
4.0	30th October 2009	Insertion to allow Chief Pharmacist to approve SOPs. Modification to allow less than one month between publication and implementation. Change to allow SOP to be updated without formal review if agreed by SOP Controller and Head of R&D (or Chief Pharmacist).
5.0	1st July 2010	Minor clarification regarding publication on website. R&D internal use of Forms and Templates explained and review process for Forms and Templates clarified. Removal of Chief Pharmacist approval.
6.0	7th November 2011	Change to include non-CTIMP procedure. Minor corrections.
7.0	5th November 2012	Removal of reference to the North and East Yorkshire R&D Alliance. General minor update.
8.0	5th March 2015	Change of R&D Manager to Head of R&D
9.0	5th December 2016	Inclusion of publication of SOPs on QPulse and change to review required every 3 years as a minimum.
10.0	15th June 2017	
11.0	18th July 2019	Change of link to R&D website. Overall review & changes to allow paperless process for review and archiving of SOP documents.

Contents

1 Introduction, Background and Purpose

The R&D Unit develops, collects and manages research Standard Operating Procedures (SOPs) on behalf of York and Scarborough Teaching Hospitals NHS Foundation Trust (the Trust). The purpose of the SOPs is to define and formalise some of the tasks that researchers and other staff have to perform in relation to research. This SOP describes the process of how SOPs are prepared, reviewed, approved and implemented, and how each step of this process is documented.

2 Who Should Use This SOP

This SOP is applicable to all members of the Trust who are involved in preparing, reviewing or controlling, approving and implementing R&D SOPs. It is also applicable to any organisation that has a current agreement with the Trust for use of the SOPs.

3 When this SOP Should be Used

This SOP should be referred to whenever an SOP is written, reviewed or approved. All R&D Unit SOPs should be prepared, reviewed and approved according to this Standard Operating Procedure.

4 SOP Procedures

SOPs are managed by the SOP Controller, who is a member of the R&D Unit and can be contacted through the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/

The most appropriate member of staff who is involved in the work described should write and prepare standard operating procedures. In some cases this may mean that an SOP has more than one author.

Unless the proposed changes are, in the view of the SOP Controller, non-substantial, SOPs should be reviewed by:

- at least one staff member who will use the SOP, in addition to the author.
- the SOP Controller will carry out quality checks on the submitted documents to ensure that the standardised format is maintained with appropriate page & section numbering, version control, summary of change history and authorship.

SOPs should be approved by the Head of R&D (or Research Adviser where the Head of R&D is the SOP author), or the relevant staff members from the Trust support departments (if SOPs relate to Pharmacy, Laboratory or Radiology), in addition to the SOP Controller.

All members of staff have a responsibility to identify changes in policy, legislation and procedures that affect R&D Unit SOPs and for bringing this to the attention of the SOP Controller. Any problems with this SOP should be notified directly to

the SOP Controller who will decide whether a formal immediate review is required. Review requests can also be submitted via Q-Pulse or via email sent to randd.sops@york.nhs.uk . Any user may choose to review an SOP at any time and may submit a review request to the SOP Controller. All review request emails/Q-Pulse notifications will be retained by the SOP Controller for consideration when the SOP is next formally reviewed, unless the changes are viewed as requiring immediate implementation.

5 How to Create a New SOP

This process is detailed as a flowchart in Appendix 1.

The following process will apply when the need for a new SOP is identified:

1. Propose a title for the new SOP to the SOP Controller.

2. The SOP Controller will add the proposed SOP title to the SOP Index and identify an author.

3. The SOP author will write a draft of the SOP using the SOP Template (R&D/T01).

4. The SOP author will identify a review team and organise a formal review.

5. The SOP Controller will send the draft SOP to the members of the review team who have agreed to provide comments/or track changes version of the reviewed document, and agree a date for completion. If comments or the reviewed track changes document are not returned by the agreed date then the SOP Controller will send a reminder email to the author. In the event of lengthy delay the author reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

6. The review team will return comments/or track changes version of the document to the author who will collate the responses, incorporate the comments and forward the final draft (along with all the draft versions) to the SOP Controller In the event of any ongoing dispute over the content of the SOP then the matter should be referred to the SOP Controller and brought to the attention of the Head of R&D.

   Note that it may be appropriate to review multiple drafts of an SOP. Each draft should have *.x* version number. For example, version 0.1 would be followed by version 0.2 and so on.

7. The SOP Controller will send the latest draft of the SOP back to the review team.

8. The review team may choose to submit further comments on the latest draft. In this case the process reverts to number 6 above. Alternatively the review team may confirm that they approve the latest draft.

9. If members of the review team confirm that they are happy with the final draft SOP then the SOP Controller will prepare the SOP for authorisation, publishing & implementation.

10. To prepare the SOP for publishing on the R&D Unit website and Q-Pulse, the SOP Controller will (i) update the version number of the SOP and the version history log, (ii) amend the watermark, and (iii) insert appropriate implementation and review dates.

11. The SOP Controller will email a final copy of the SOP/Form/Template to the Head of R&D (or delegate) for approval. Once the document is approved the first two pages will be printed off and signed by the Head of R&D (or delegate) and the SOP Controller. These two pages will then be scanned and the copy saved in the relevant SOP folder on the x drive. Copy of the email correspondence will be retained in the document folder on X drive to ensure complete audit trail of the approval process.

12. A copy of the SOP, Form and/or Template will be uploaded onto Q-Pulse by the SOP Controller, and an alert issued to research staff to ask them to train on the SOP.

13. The electronic copy of the SOP will then be saved to the R&D Unit's SOPs folder located on the x drive.

6 How to Formally Review an SOP

All R&D Unit SOPs will indicate when they require periodic review. However, review schedules will be modified if changes to the legislation necessitate expedited or immediate revision of R&D Unit SOPs.

When issuing SOPs, the SOP Controller will make note of the review date on all SOPs, however, it is the responsibility of any user of the SOP to notify the SOP Controller immediately if they believe any R&D Unit SOP requires updating before the scheduled time.

All SOPs should be reviewed on or before their proposed review date regardless of whether it is envisaged that changes will be required.

If an existing SOP is due for review or has been identified as requiring review:

1. The SOP Controller will create a new *.x* draft of the SOP document. For example, if the last published version was Version 1 the next draft would be Version 1.1.

2. The original author will review the SOP and determine whether an update is required. If the original author is unavailable/or no longer responsible /or no longer the most appropriate to review the procedures outlined in the document then an alternative author will be identified.

3. The author may review the SOP and decide that there is no update required at that time. The SOP author must inform the SOP Controller in writing that no update is required and that the SOP is current. In this event the version number of the current SOP would remain unchanged but a note would be made in the Version History Log to state that the document was reviewed and required no change. If an update is required then the SOP author will identify an appropriate review team, initiate a formal review process and prepare an updated version of the SOP. If

possible, previous reviewers and current users should be included in the review team.

4. The authorship of the updated SOP versions will be co-ordinated by the SOP Controller. If the review author is different to the original author and the changes made are considered significant, the authorship should be transferred to the new author. If the changes are minor, an agreement should be made between the SOP Controller, the original author and author of the changes regarding the overall authorship of that document.

5. The SOP Controller will send the draft SOP to the review team and agree a date for return of comments/ or track changes version of the document. The SOP author should ensure that comments are received from all parties who expressed an initial intention to review the document(s). . In the event of lengthy delay the SOP author r reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

6. The review team will return comments/or track changes version of the document to the author who will collate the responses. The author will submit the revised SOP (along with all draft versions) incorporating the comments of the review team to the SOP Controller.

   Note that it may be appropriate to review multiple drafts of an SOP. Each draft should have *.x* version number. For example, version 1.1 would be followed by version 1.2 and so on.

7. The SOP Controller will send the latest draft of the SOP back to the review team.

8. The review team may choose to submit further comments on the latest draft. In this case the process reverts to number 6 above. Alternatively the review team may confirm that they approve the latest draft.

9. If the review team confirm that they are happy with the draft SOP then the SOP Controller will prepare the SOP for publishing. In the event of any ongoing dispute over the content of the SOP then the matter should be referred to the SOP Controller and brought to the attention of the Head of R&D.

10. To prepare the SOP for publishing on the website and Q-Pulse, the SOP Controller will (i) update the version number of the SOP (if required) and the version history log, (ii) amend the watermark, and (iii) insert appropriate implementation and review dates.

11. The SOP Controller will email a final copy of the SOP/Form/Template to the Head of R&D (or delegate) for approval. Once the document is approved the first two pages will be printed off and signed by the Head of R&D (or delegate) and the SOP Controller. These two pages will then be scanned and the copy saved in the relevant SOP folder on the x drive. The document(s) will be uploaded to Q-Pulse and the R&D Unit website. Copy of the email correspondence will be retained in the document folder on X drive to ensure complete audit trail for the approval process

12. A copy of the SOP, Form and/or Template will be uploaded onto Q-Pulse by the SOP Controller, and an alert issued to research staff to ask them to train on the SOP.

13. The electronic copy of the SOP will then be saved to the R&D Unit's SOPs folder located on the x drive.

7 How To Manage SOPs

R&D SOPs are only valid as they appear on the SOP website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and Q-Pulse. The SOP Controller is responsible for publishing SOPs on this site and on Q-Pulse.

An established and validated document management system should be followed by the SOP Controller for all R&D Unit Standard Operating Procedures, Forms, Templates and Guidance Documents:

1. A central repository of documents containing evidence for all steps undertaken when creating, reviewing, controlling, approving and implementing R&D Unit SOPs (as detailed in the sections above) will be maintained by the R&D SOP Controller (or a delegated individual in his/her absence) and saved on R&D shared drive (Applied Learning (\\vsx01(X:)/ SOPs) with access restricted to the following staff members:

   SOP Controller (SOPs folder owner with read & write access)
   Head of R&D (view only)
   Research Adviser (view only)
   Research QA Manager (read & write access to cover for any long term absence/sickness when authorised by the Head of R&D)

2. An up to date SOP index and review history log for all SOP documents will be maintained by the SOP Controller (including information on the responsible people, review status and key communication related to each copy). Periodic quality checks for review dates, progress with new drafts and reviews, quality checks of the submitted and saved documents (format, page/section numbering, content display, authorship, and quality of scanned & archived copies) will be carried out by the SOP Controller and reported as part of the R&D Unit Quarterly QA Meetings.

3. Water marks (draft & uncontrolled when printed) will be used to identify controlled copies downloaded from either the X drive central repository or the R&D website or Q-Pulse. For current version staff should always refer to either the website or Q-Pulse, printed out paper copies or downloaded PDF documents should always be checked that the version number and date are the most recent one as shown on the R&D Unit website. This is described on the front cover of all SOPs.

4. The final documents approved & signed off by the Head of R&D will be published on the R&D Unit Website, and uploaded to Q-Pulse (electronic document management system) for training purposes. Please see R&D SOP/S22 outlining the self-directed training requirements for R&D SOP documents. The wet ink signature pages

documenting formal SOP approval and Version History Log will be scanned and saved alongside the final PDF version (read-only) of the approved SOP document on R&D X drive (Applied Learning (\\vsx01(X:)/ SOPs). This process will be carried out by the SOP Controller following established steps to ensure that the obtained copies can be certified as valid and paper copies destroyed.

5. Published SOPs should have a version number (for example Version 1.0). Draft versions of SOPs should have a new *.x* version number (for example Version 1.1). Draft SOPs should have a Draft watermark. Published SOPs should have a 'Uncontrolled document when printed' watermark.

6. The standard style, layout and content of SOPs are defined in the SOP Template (R&D/T01) which is available on the SOPs page of the R&D Unit website and Q-Pulse (www.research.yorkhospitals.nhs.uk/sops-and-guidance-/). SOPs written by the R&D Unit should have the prefix R&D for ease of distinction as other SOPs developed by integrated units may appear on the R&D Unit's website.

7.1 Forms and templates

Forms and Templates should be numbered with an F or T prefix (for example R&D/F01). SOP users are strongly encouraged to use all R&D Unit Forms and Templates as referred to in the SOPs. Forms and Templates will be available to download in a Word format to enable the manipulation of the document that is likely to be required for use. Forms and Templates intended only for internal R&D Unit use may not be published on the R&D Unit website.

All forms and templates should be associated with a SOP and not stand alone documents to ensure they are subject to regular review.

Forms and Templates are reviewed as and when the need for changes to them is identified.

When a SOP is reviewed the review should include scrutiny of any directly associated Forms and Templates listed in the 'Related Documents' section.

8 What to Do If There Is More Than One SOP

Some trials are supplied with SOPs. Other trials include sections in the protocol that contradict the procedures issued by the R&D Unit, or recommend the use of SOPs issued by a trials unit or company. Some trials may be co-sponsored, each sponsor with their own SOPs. In these cases it is important to be clear which SOP to use.

The SOPs supplied by the R&D Unit should be considered the default procedures to be used for all projects in the Trust except where project-specific procedures are specified, or referred to, in the protocol. Where they exist, project-specific procedures take precedence. Careful consideration must be given at study set up as to which SOPs will apply to a specific trial. Full details must be included as a written statement in the study site file (File Note). If there

are any doubts about which SOP to use they should be referred to the SOP Controller.

9 Training

The R&D Unit will notify staff of SOPs developments using the Q-Pulse notification system. Alerts will be issued to all users registered to receive them. It is the responsibility of all research active staff to ensure that they respond to alerts issued for updates. Detailed procedure for self-directed training in York Foundation Trust R&D Unit Standard Operating Procedures is outlined in R&D/S22

10 Suspending or Withdrawing SOPs

An SOP may be suspended or withdrawn as necessary. If an SOP describes a process that is no longer followed, then it should be withdrawn from current use and archived. The SOP Controller will provide notification of a suspended or withdrawn SOP to relevant individuals via email. This email will include:

- The SOP name, version number and date
- A brief explanation of why the SOP has been suspended or withdrawn

11 Archiving SOPs

Superseded versions of approved SOP documents will be archived electronically on X-drive, including the complete audit trail and scanned signature pages.

All SOP documents currently archived as per R&D SOP/S01 v.1.0 – v.10.0 that originally were maintained & sent to archives in paper format, will be retrieved, scanned and transferred onto the X Drive restricted access folder for long term archiving. Any documents that are currently available in paper format only (and are not duplicate copies of the documents already saved electronically) will be assessed for relevance and scanned for electronic archiving. Signature page & version history log will be scanned for all paper SOP, Form, Template and Guidance documents. The process of scanning paper documents will be carried out by the SOP Controller to ensure consistency & to make sure that no information is lost or altered. Systematic checks will be performed to ensure quality and allow destruction of the original paper documents. The quality checks will include the following:

- accuracy of file name; including that it is marked as a superseded version of an already existing document;
- quality of the image (suitable resolution to allow readability as per the original; has any content e.g. header information, hole-punch images, that appears on the original document been removed from the digital image)
- the audit trail associated with the document

The X drive used for electronic archiving (Applied Learning (\\vsx01(X:)/ SOPs) is maintained, including back up and disaster recovery plan, as per the Trust Information Security Policy ensuring that the confidentiality, integrity and availability of the Trust business critical systems and data is protected.

12 Standards

All staff should be aware that local Trust policies and procedures apply when planning and undertaking studies.

All investigators should be aware of their responsibilities under ICH-GCP, UK Law, the Declaration of Helsinki and other relevant regulations.

All individuals involved in the preparation, review and approval of R&D Unit SOPs have a responsibility to check that the documents reflect the correct current policy and legislation.

13 Related SOPs

Sections of this SOP refer to:

R&D/T01 SOP Template

Available from: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/

14 Appendix 1 – Flow diagram