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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	R&D/S01
Version Number:	10.0
Author:	Deborah Phillips
Implementation date of current version:	15th June 2017

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

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	

Contents

1 Introduction, Background and Purpose

The R&D Unit develops, collects and manages research Standard Operating Procedures (SOPs) on behalf of York Teaching Hospital 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 how SOPs are prepared, reviewed, approved and implemented.

2 Who Should Use This SOP

This SOP is applicable to all members of the Trust who are involved in preparing, reviewing or controlling R&D SOPs. It is also applicable to any organisation that has a current contract 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.northyorksresearch.nhs.uk/sops.

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.

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. Any user may choose to review an SOP at any time and may submit a review form containing comments to the SOP Controller. All review forms will be retained by the SOP Controller for consideration when the SOP is next formally reviewed.

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 Controller and author will identify a review team and the SOP Controller will organise a formal review.

5. The SOP Controller will contact the proposed reviewers to determine whether they would be willing and able to provide a review of the SOP.

6. The SOP Controller will send the draft SOP to the members of the review team who have agreed to provide a proposed date for return of comments. The SOP Controller will endeavour to ensure that comments are received from all parties who expressed an initial intention to review the document(s). If comments are not returned by the proposed date then the SOP Controller will send a reminder email. In the event of lengthy delay the SOP Controller reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

7. The review team will return comments to the SOP Controller who will collate the responses and forward them to the SOP author.

8. The SOP author will incorporate the comments from the review team.

   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.

9. The author will submit the revised SOP incorporating the comments of the review team to the SOP Controller

10. The SOP Controller will send the latest draft of the SOP incorporating the initial comments of the reviewers back to the review team.

11. The review team may choose to submit further comments on the latest draft. In this case the process reverts to number 7 above. Alternatively the review team may confirm that they approve the latest draft.

12. If members of 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 will be referred to the R&D Group.

13. To prepare the SOP for publishing on the 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.

14. A paper copy of the final SOP will be printed, then approved, signed and dated by the Head of R&D (or delegate) and the SOP Controller. A copy of the signed approved version will be uploaded onto the R&D Unit website at www.northyorksresearch.nhs.uk/sops as a read only document. Templates and Forms will not appear as read-only documents but will be available as downloadable Word documents for ease of use.

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

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

17. The original approved signed and dated copy will be stored in the SOP archive folder within the R&D Unit.

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 then an alternative author will be identified.

3. The author may review the SOP and decide that there is no update is 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. The process would then move to point 14. 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.

4. If an update is required then the SOP author will prepare an updated version of the SOP.

5. The SOP Controller and author will identify an appropriate review team and the SOP Controller will organise a formal review. If possible, previous reviewers and current users should be included in the review team. If both the SOP Controller and Head of R&D agree that the update does not require formal review (e.g. where proposed changes are typographical or concern minor uncontentious clarification) then this decision will be documented and the process will proceed to point 14.

6. The SOP Controller will contact the proposed reviewers to determine whether they would be willing and able to provide a review of the SOP.

7. The SOP Controller will send the draft SOP to the review team a proposed date for return of comments. The SOP Controller will endeavour to ensure that comments are received from all parties who expressed an initial intention to review the document(s). If comments are not returned by the proposed date then the SOP Controller will send a reminder email. In the event of lengthy delay the SOP Controller reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

8. The review team will return comments to the SOP Controller who will collate the responses and forward them to the SOP author.

9. The SOP author will incorporate the comments from the review team.

   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.

10. The author will submit the revised SOP incorporating the comments of the review team to the SOP Controller.

11. The SOP Controller will send the latest draft of the SOP incorporating the initial comments of the reviewers back to the review team.

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

13. 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 will be referred to the R&D Group.

14. 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.

15. A paper copy of the final SOP will be printed, then approved, signed and dated by the Head of R&D (or delegate) and the SOP Controller. A copy of the signed approved version will be uploaded onto the R&D Unit

website at www.northyorksresearch.nhs.uk/sops as a read only document. Templates and Forms will not appear as read-only documents but will be available as downloadable Word documents for ease of use.

16. 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.

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

18. The original approved signed and dated copy will be stored in the SOP archive folder within the R&D Unit.

7 How To Manage SOPs

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

The SOP Controller will store a complete archive of paper copies of signed, approved versions of the SOPs. It may be necessary for users to keep other paper copies for ease of use. However it should be remembered that the definitive versions of all R&D Unit SOPs appear online, so the person using a particular SOP should always check that they have the latest version before they use it. This is described on the front cover of all SOPs.

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. SOPs under review should have a watermark stating that they are 'under review'. Published SOPs should have a 'Uncontrolled document when printed' watermark.

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.northyorksresearch.nhs.uk/sops.html). 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.

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. 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 SOP/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

Paper copies of all signed, approved and published R&D SOPs will be stored in a locked and fireproof filing cabinet within the R&D Unit. After 3 years, paper copies of superseded SOPs will periodically be archived in accordance with the Trust's policy on archiving essential trial documentation. This archive will be retained indefinitely.

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.northyorksresearch.nhs.uk/sops.

14 Appendix 1 – Flow diagram