York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S26

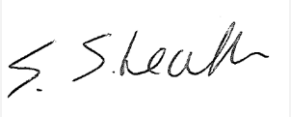
Preparation, Review and Approval of Study-Specific Standard Operating Procedures for Research

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	R&D/S26
Version Number:	6.0
Author:	Deborah Phillips
Implementation date of current version:	11th August 2020

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	14th July 2020
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	14th July 2020

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	21st September 2009	
2.0	11th March 2011	Changes to allow the R&D Unit to undertake the preparation, review and approval of study-specific SOPs in cases where the SOP is only relevant to the processes of the R&D Unit.
3.0	28th November 2011	Change to SOP Controller. Removal of section 7. Change to Forms and Template referenced.
4.0	6th January 2014	Removal of references to the North and East Yorkshire R&D Alliance.
5.0	15th June 2017	Two year review
6.0	11th August 2020	Change of links to R&D unit website. IRAS number for identification where EudraCT is N/A

Contents

1 Introduction, Background and Purpose

This SOP describes how study-specific SOPs are prepared, reviewed, approved and implemented for studies sponsored or co-sponsored by the Trust.

Research groups are strongly advised to give early consideration as to whether study-specific procedures can be incorporated into the protocol so as to avoid unnecessary preparation of study-specific SOPs.

2 Who Should Use This SOP

For all studies sponsored or co-sponsored by the Trust, it is expected that R&D Unit research SOPs will apply. All R&D Unit research SOPs are managed by the SOP Controller and can be contacted through the R&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/.

In circumstances when study-specific SOPs are required then the responsibility for preparing and reviewing these is normally delegated to the Chief Investigator (CI). The CI may in turn delegate this responsibility to an appropriate member of staff. However there may be circumstances where a study-specific SOP is required for clarification to specific R&D procedures in relation to a particular trial, in which case the preparation, review and approval of these documents will be undertaken internally by the R&D Unit.

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

Study-specific SOPs should be reviewed by:

- the Chief Investigator (CI) for the study (unless the CI has delegated responsibility for this or the R&D unit is responsible for the SOP)
- at least one staff member who will use the SOP, in addition to the author.
- the SOP Controller.

SOPs should be approved by the study CI (or Head of R&D where the R&D unit is responsible for the SOP) and the SOP Controller. If the SOP relates to Pharmacy, Laboratory or Radiology issues then the relevant staff members from that support department should also approve the SOP.

All members of staff have a responsibility to identify changes in policy, legislation and procedures that affect research 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.

3 When this SOP Should be Used

For studies sponsored or co-sponsored by the Trust this SOP should be referred to whenever a study-specific SOP is required to be written, reviewed or approved.

4 How to Create a New SOP

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

1. Propose a title for the new study-specific SOP to the SOP Controller.

2. The SOP Controller will add the proposed SOP title to the SOP Index, and provide a reference number for the SOP. The CI will then be contacted to assist in identifying an appropriate author.

3. The SOP author will write a draft of the SOP using the SOP Template (R&D/T08).

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

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

6. The SOP author will send the draft SOP to the members of the review team who have agreed to provide a review with a proposed date for return of comments. The SOP author 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 author will send a reminder email. In the event of lengthy delay the SOP author reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

   Note that SOP review may also take place in another format (e.g. at review meetings) if this is more appropriate. In such instances the review process and the identity of those involved must be clearly documented and this documentation retained as evidence of appropriate review.

7. The review team will return comments to the SOP author who will collate the responses and incorporate them into a revised draft of the SOP.

   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.

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

9. 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. Approval of the SOP and the names of those who gave approval must be documented.

10. If members of the review team confirm that they are happy with the draft SOP then the SOP author 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 Chief Investigator.

11. To prepare the SOP for publishing, the SOP author (or other delegated individual) 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.

12. The SOP author (or other delegated individual) will be responsible for ensuring that a reminder is set for an appropriate point in time to notify that review of the SOP is scheduled.

13. A paper copy of the final SOP will be printed, then approved, signed and dated by the CI for the study and the R&D Unit SOP Controller. The authorisation signature of the CI will confirm that the SOP meets appropriate standards. The SOP Controllers authorisation will indicate only that the use of the SOP in the proposed study does not contradict other R&D Unit SOPs being used.

14. The SOP author (or other delegated individual) is responsible for ensuring that original approved signed and dated copy is stored in an appropriate study file (ISF/TMF) together with all of the review documentation.

5 How to Formally Review an SOP

All study-specific 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 SOPs.

When issuing SOPs, the SOP author (or delegated individual) will be responsible for ensuring that appropriate reminders are in place to ensure review dates are adhered to. It is the responsibility of any user of the SOP to notify the SOP author immediately if they believe any study-specific SOP requires updating before this time.

All SOPs should be reviewed on 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 author 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 process would then move to point 11. 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 author will identify an appropriate review team and will organise a formal review. If possible, previous reviewers and current users should be included in the review team.

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

7. The SOP author will send the draft SOP to the review team with a proposed date for return of comments. The SOP author 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 author will send a reminder email. In the event of lengthy delay the SOP author reserves the right to identify an alternative reviewer, or continue the review process in the absence of a reviewer's comments.

   Note that SOP review may also take place in another format (e.g. at review meetings) if this is more appropriate. In such instances the review process and the identity of those involved must be clearly documented and this documentation retained as evidence of appropriate review.

8. The review team will return comments to the SOP author who will collate the responses 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.

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

10. 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. Approval of the SOP and the names of those who gave approval must be documented.

11. If the review team confirm that they are happy with the draft SOP then the SOP author 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 Chief Investigator.

12. To prepare the SOP for publishing, the SOP author (or other delegated individual) 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.

13. The SOP author (or other delegated individual) will be responsible for ensuring that a reminder is set for an appropriate point in time to notify that review of the SOP is scheduled.

14. A paper copy of the final SOP will be printed, then approved, signed and dated. The authorisation signature of the CI will confirm that the SOP meets the standards set out in section 11. The SOP Controller's authorisation will indicate only that the SOP does not contradict other

R&D Unit SOPs. Other signatures will be obtained as required (e.g. Pharmacy).

15. The SOP author (or other delegated individual) is responsible for ensuring that original approved signed and dated copy is stored in an appropriate study file (ISF/TMF) together with all of the review documentation.

6 How To Manage SOPs

The CI (or delegated individual) will store a complete archive of paper copies of signed, approved versions of the study-specific 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 study-specific SOPs must be retained and individuals 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.

Where paper copies of older versions of an SOP exist, the person using the SOP should put a line through the front page of the superseded version and write "superseded" across the top. Superseded versions should be kept in site study files to enable identification of the version in use when any particular step was taken in the research.

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 study-specific SOPs are defined in the SOP Template (R&D/T08) which is available on the SOPs page of the R&D Unit website (https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/). Study-specific SOPs written by study teams should be named as follows:

study short title/EudraCT number (or IRAS number where EudraCT is N/A)/SXX.

Forms and templates associated with study-specific SOPs should be reviewed, approved and published in the same way as SOPs. They should be numbered with an F or T prefix.

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

7 Training

When a new SOP is authorised, or when an existing SOP is revised, as a minimum self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their study specific training record. The CI (or delegated individual) is responsible for ensuring that there is adequate time for appropriate SOP training for all relevant staff before the SOP is formally implemented. 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.

8 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 CI (or delegated individual) will be responsible for providing 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

9 Archiving SOPs

Paper copies of all signed, approved and published study-specific SOPs will be stored in the study ISF/TMF, in a locked and fireproof filing cabinet while the study is ongoing. At the end of the study then study-specific SOPs will be archived with the ISF/TMF in accordance with R&D/S11 (archiving).

10 Standards

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

All Clinical research studies should be conducted to Good Clinical Practice (GCP) standards. All investigators should be aware of their responsibilities under ICH and UK Law.

All study-specific SOPs should take into account the standards relevant to the planned study.

11 Related SOPs

R&D/T08 Study-specific SOP Template

R&D/S11 Archiving

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