


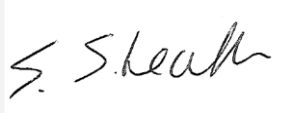
Amendments: Quick Guide

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Version Number:	2.0
Author:	Mark Aldous
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	13 th July 2022
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	13 th July 2022

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	31 st August 2020	
2.0	15 th August 2022	Change to initial notification of amendment

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1 Introduction, Background and Purpose

This SOP describes the procedure for implementation of amendments to the protocol other essential documents or study arrangements for research studies not sponsored by, but taking place within, the Trust.

2 Who Should Use This SOP

This SOP is aimed at Principal Investigators (PIs), research staff and staff in all involved service departments in the Trust where externally-sponsored research studies are hosted.

In this SOP the Trust means York and Scarborough Teaching Hospitals NHS Foundation Trust and applies to all sites within the Trust.

3 When this SOP Should be Used

This SOP should be used:

- when notification is received that an amendment has been made to a research study;
- when the RSI (Reference Safety Information) have been updated for an externally sponsored clinical trial of an investigational medicinal product (CTIMP).

For CTIMP studies the RSI should be clearly identified in the protocol and specified in the Clinical Trial Authorisation application. The study sponsor should clearly define the RSI for a trial, for example a clearly defined section of the IB (Investigator Brochure) or SmPC (Summary of Product Characteristics).

Please note: The entire IB or SmPC is not the RSI, but a clearly defined section within this document. Investigators should confirm with the study sponsor if there is any uncertainty as to where to locate the RSI or what the current version of the RSI is. Any changes to RSI should be submitted to all Sites as a substantial amendment.

4 Procedure(s)

Email notification received from the CTA Support email address (having being received from Research Governance) .

Check the email and attachments to establish:

- Amendment number
- Amendment category (see R&D/S07)
- What study changes/updates are involved (*Does it involve any of the support departments? Anything with sampling/IMP or radiology scans?*)
- What external approvals are in place and what are still awaited (HRA/REC/MHRA)

Create a sub-folder in the study folder's amendment section on the Q drive. Copy all documentation to this folder.

Make a start on completing the R&D/F18 (amendment checklist). Fill it out as far as possible. As the amendment progresses it must be kept up-to-date in case of staff cover/workload issues

Some non-substantial amendments can be implemented immediately without approvals or CAC; however Research Governance has asked that we always clarify this with them.

Send the original email (with the attachments) out to the PI, the senior research nurse that oversees the Care Group, the lead research nurse for the study, Research Governance, Research QA (*for any studies that involve Radiology support/involve imaging*), Labs (*for any studies that involve Laboratory samples*) and Pharmacy (*for CTIMP studies only*) and c.c. in the sponsor.

Support departments must be kept informed and work to up-to-date protocols. Please bear in mind that even if Labs and Radiology are not initially/currently involved in the study, they may become involved as a result of an amendment. They must be kept aware of any study developments and changes that may require their support. However, they do not need to be emailed about amendments to simple observational data collection studies. Please always check with the Research Nurses/Team if you are not sure.

In the email give a brief description of what the amendment involves, what approvals are already in place and what approvals are awaited. Also, state the length of time in days that we have to approve the changes. This is usually 35 days from the date that we receive notification of the amendment.

Keep a close eye on any communication from the sponsor (things can change quickly).

If the amendment involves localising updated documentation, do this now and save as "localised" in the amendment folder awaiting implementation.

Keep the electronic R&D/F18 form up to date as the approvals come in, and save all amendment related emails to the amendment sub-folder.

Once all the necessary approvals are confirmed, R&D will issue CAC. As soon as this is received contact the study team, relevant support departments and the study sponsor to agree a local implementation date.

Once implementation is agreed email the PI, study lead research nurse and the relevant support departments, c.c. in the sponsor to say the amendment will be implemented on the agreed date.

Ensure all current localised versions of documents are added to the relevant part of the ISF and to the sub-folder in the electronic study folder. Make sure all old versions are superseded. New version documents may need taking to clinical areas and old version documents removed. Sometimes the sponsor will send a new document version check list (especially if there are several new version documents as a result of the amendment). Once this is completed, print off all the amendment documentation and key correspondence and collate them together in a plastic pocket ready to be added to the ISF.

Add the amendment to the amendment log (R&D/F118). Keep track of versions – complete Version Control Log- R&D/F101 (*if not provided by the sponsor*).

File the pocket in the relevant section of the ISF, ensure the electronic study folder is up to date & correct localised versions are easy to find and available for printing as required.

Finally, do a last check of the R&D/F18 (amendment checklist) to make sure it's fully completed. This form is a quick reference guide to the dates and the processing of the whole amendment so must be completed in full.

Quick Guide Prompts:

1. Amendment email notification received from Research Governance or study sponsor.
2. Create a sub-folder in the study folder's amendment section on the Q drive and copy all related documents to it.
3. Make a start on completing the R&D/F18 (amendment checklist).
4. Send the original email (with the attachments) out to the York teams for their approvals.
5. Localise updated/new version documents in readiness for implementation.
6. Print off all the amendment documentation and collate together in a plastic pocket.
7. Once all necessary approvals are confirmed Research Governance will issue CAC.
8. Contact the local study team, support teams & sponsor and agree an implementation date (sponsor green light).
9. Once date agreed email all to advise of implementation.
10. Make sure all documentation is correct in the ISF and in the electronic folder and that all old documents are superseded.

5 Related SOPs and Documents

R&D/S07	Implementing Amendments for Research Studies NOT Sponsored by the Trust
R&D/F18	Amendment Checklist (Research Teams)
R&D/F101	Document Version Control Log
R&D/F118	Amendment Log