

R&D Processing of Amendments

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Date:	8 th April 2019

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	14 th November 2011	
2.0	13 th May 2013	Removal of references to the North and East Yorkshire R&D Alliance. Change of author and updating of process.
3.0	7 th April 2014	SOP amended to reflect current practice including CSP.
4.0	26 th September 2016	Re-write to incorporate the new HRA process
5.0	21 st February 2019	Change to link to R&D website Addition of Workflow Update to Unit Admin Actions
6.0	6 th May 2019	Research Delivery Facilitators removed as being the primary people who process amendments. Note added to explain who is responsible for the processing of amendments upon significant absence of the Administrative Co-ordinator or if the amendment is deemed to be complex.

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1 Introduction, Background and Purpose

This SOP describes the procedure for R&D Unit review and acknowledgement processes for amendments to research studies.

2 Who Should Use This SOP

This SOP is aimed at:

1. R&D Unit personnel, who manage the sponsorship of research studies on behalf of the Trust;
2. R&D staff who manage the review of amendments for externally sponsored research studies hosted by the Trust.

3 When this SOP Should be Used

This SOP should be used when an amendment is received by the R&D Unit for either a Trust Sponsored study or for an externally sponsored study taking place within the Trust.

4 R&D Unit Receipt and Acknowledgment of Amendments

When a notifiable amendment is received by the R&D Unit (by e-mail), the Administrative Coordinator will:

1. Access EDGE to check that the study is logged and currently active within the Trust.
2. Create an amendment sub-folder within the study folder on the X:Drive and save a copy of the notification and documents
3. .In EDGE add the Amendment Workflow on the 'RED local page of the study. This is done by
 - clicking the Workflow Tab near the top of the page
 - click the Add button on the top right. In the comment box add the number of the amendment e.g. SA1 & save.
 - The amendment process will now be highlighted with a flag – Red – Not started, Amber – in process, Green – Completed.
 - Click the Amendment Process. There are 12 stages to complete with the process of each stage explained by clicking 'show procedure'
 - Click on each stage as & when completed & add date of completion. Provide comments at each stage if necessary.

This process allows anyone with access to the study to see the status of the amendment

4. Check which support departments are involved in the study (either from the staff tab on EDGE or from the original NHS permission letter/checklist). . Forward the email and documents to the research team and to any support departments asking them to confirm that they are happy for the amendment to be implemented or to highlight any issues, or reasons why the amendment cannot be implemented.
5. Once all approvals are received & the research team and support department(s) are happy then reply to the Sponsor from the original email,

confirming Continuing Capacity & Capability and copy in the Research Team & supporting departments

R&D Unit Admin Actions

6. Save copy of confirmation email onto the X:drive along with all approvals from the Team & Supporting Departments. Upload all documents relating to the amendment into EDGE& the Amendment folder.
Add new PIS, PCF & Protocols etc to the relevant folders on EDGE and supersede the existing versions

Exceptions

7. If an amendment includes changes to Radiology procedures then a new IRMER form may be required.
8. Research Delivery Facilitators should pass such amendments to the R&D Manager to review.

Note; In the absence of the Administrative Co-ordinator for a significant amount of time the Research Administrative Co-ordinator (RACo) or the Research Delivery Facilitators (RDFs) will complete the above noted required amendment processing actions.

Note; RDFs and the RACo may also complete some or all of the above noted actions relating to the processing of amendments if the amendment is deemed to be complex and requiring their input. This may for example be when a new arm is added into an existing study or some additional tests are required that would mean a re-assessment by the support departments and a contract amendment.

5 Related SOPs and Documents

R&D/S07 Implementing Amendments for Research Studies Sponsored by the Trust

R&D/S74 Making Amendments to Trust Sponsored Research Studies

R&D/T06 Amendment No Objection Email