York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit Standard Operating Procedure R&D/S75



## **R&D Processing of Amendments**

# IT IS THE RESPONSIBILITY OF <u>ALL</u> 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: 19<sup>th</sup> July 2022

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 <sup>th</sup> November 2011			
2.0	13 <sup>th</sup> May 2013	Removal of references to the North and East		
		Yorkshire R&D Alliance. Change of author		
		and updating of process.		
3.0	7 <sup>th</sup> April 2014	SOP amended to reflect current practice		
		including CSP.		
4.0	26 <sup>th</sup> September 2016	Re-write to incorporate the new HRA process		
5.0	21 <sup>st</sup> February 2019	Change to link to R&D website		
		Addition of Workflow		
		Update to Unit Admin Actions		
6.0	6 <sup>th</sup> 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		
7.0	4.0th A	be complex.		
7.0	16 <sup>th</sup> August 2022	New process added to ensure all amendments		
		are logged by CTA Support		
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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 C&C Summary Info on the EDGE Attributes or from the original NHS permission letter/checklist). Forward the email and documents to CTA Support informing which (if any) support departments are involved and also

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if includes Scarborough. Ask them to process the amendment and highlight any issues, or reasons why the amendment cannot be implemented. If the amendment involves an extension to the study, the email & documents need to go to Senior Research Nurses first. Once they have approved, then forward to CTA Support and proceed as above (see attached Workflow)

 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

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Notification of Amendment received to Research.Governance@York.NHS.UK Notification of Amendment received to Research Teams/ CTAs/PIs' inbox

Forward the received AM to Research.Governance@York.NHS.UK

Research.Governance@York.NHS.UK reviews the amendment details – any amendments extending the project timelines or scope (e.g. adding new arm) please send to SeniorResearchNurse@YORK.NHS.UK for no objection review

<u>SeniorResearchNurse@YORK.NHS.UK</u> review and respond within 1 working day to Research.Governance@York.NHS.UK

If no objection confirmed by SRNs, <a href="mailto:Research.Governance@York.NHS.UK">Research.Governance@York.NHS.UK</a> starts the Amendment review process:

- start EDGE workflow
- specify which support departments are involved
- email it to CTA Support CTASupport@york.nhs.uk for processing

<u>CTASupport@york.nhs.uk</u> assigns the received Amendment to a CTA – within 1 working day

The assigned CTA starts the local review process:

- Add it to the workload spreadsheet
- Request CG/ RNs review and approval
- Request PI review and approval
- Request Support departments review and approval
- Collate all responses and forward to <u>Research.Governance@York.NHS.UK</u>

CTA checklist:

- ✓ Follow the Amendments Checklist F18
- ✓ Are there any delays?/ can we confirm continuing CaC within 35 days? – please make sure the study sponsor is kept informed
- Please make sure all parties are kept up to date with the progress

Research.Governance@York.NHS.UK updates the workflow, confirms continuing CaC to the sponsor & triggers local implementation

The assigned CTA starts local implementation:

- Agree implementation date with the CG/ RNs & PI and support departments
- Inform the study sponsor
- Make sure the Amendment changes are implemented by the end of the day on the agreed date

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