York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S75

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	R&D/S75
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Authors:	Angela Jackson
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	22nd September 2016
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	22nd September 2016

This SOP will normally be reviewed every 2 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	14th November 2011	
2.0	13th May 2013	Removal of references to the North and East Yorkshire R&D Alliance. Change of author and updating of process.
3.0	7th April 2014	SOP amended to reflect current practice including CSP.
4.0	26th September 2016	Re-write to incorporate the new HRA process

Contents

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 **Research Delivery Facilitators** 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. Check that HRA Assessment & Approval are included in the documents, along with REC Approval & MHRA if required.
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. If 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 (only if HRA Approval has been received.) Add details of the amendment into the File tab on EDGE in the Amendments folder.

R&D Unit Admin Actions

6. Save copy of confirmation email onto the X:drive & EDGE
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.

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