York Foundation Trust R&D Unit
SOP
R&D/78

Processing Amendments in the Laboratory Research Team

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Jessica Goodliffe
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	24th August 2022
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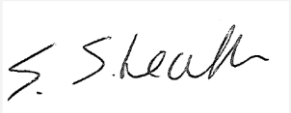
	Signature:	
	Date:	24th August 2022

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	16th October 2017	
2.0	21st September 2022	Section 4.3: • Information added to detail reviewing amendments that don't require study-wide review (not previously in SOP). • Information added to detail reviewing amendments for studies involving standard care pathway (previously in section 4.6). • Deleted some of detail in step 5 of section 4.3 detailing how to process amendments that require no changes to Laboratory Research procedures. Merged this information into section 4.4 to state that such amendments still require acceptance via Research Governance. Section 4.4: • Changed to detail how to confirm acceptance/rejection or acknowledgment of all amendments, rather than just those with impact on labs. • Split into bullet points to show more clearly different processes that may be followed to accept/reject or acknowledge amendments. Section 4.5: • Changed to detail local implementation of all amendments, rather than just those with impact on labs. • Amended to detail differences in processes for studies involving standard care pathway, as section 4.6 merged. Section 4.6: merged into previous sections. Text referring to Appendix A deleted as no appendix present. Change of author

Contents

1 Introduction, Background and Purpose

The procedures describing processing and implementing of amendments to studies being conducted within York Teaching Hospital NHS Foundation Trust are described in the following SOPs:

- Implementing amendments for research studies NOT sponsored by the Trust (R&D/S07);
- Making amendments to Trust Sponsored Research studies (R&D/S74);
- R&D processing of amendments (R&D/S75);

These procedures stipulate that the Laboratory Research Team should be informed of any amendments within studies that involve the Research Laboratory Service. There is also a requirement that Laboratory authorisation, for the amendment to proceed, is obtained prior to its implementation.

The Laboratory Research Team should be notified of amendments to ensure that:

- Laboratory staff are in receipt of all of the correct versions of study documentation e.g. Protocol & Laboratory Manual that may have changed as a result of the amendment.

- Changes can be made to Laboratory documents if required e.g. Laboratory Instructions, study specific SOP.

- Labs are able to continue to support the study taking into account; costs, workload, other resource implications, and practical aspects of the processing, storing and shipping of study samples including any specific staff training that may be required.

The purpose of this SOP is to describe the process for reviewing and implementing an amendment to a research study in Labs.

2 Who Should Use This SOP

This SOP should be used by all members of the Laboratory Research Team, Principal Investigators, Research Staff and the R&D Unit who are involved in processing amendments that require the Laboratory Research Service.

3 When this SOP Should be Used

This SOP should be used when a notification is received that an amendment has been made to a research study which requires Laboratory Research Services.

4 Procedure(s)

4.1 Amendments and their classification

Amendments are changes made to a research study after review body approval has been received. An amendment can be either:

- Substantial; an amendment to the terms of the application, or to the protocol or any other supporting documentation that is likely to affect the safety or mental integrity of participants, the scientific value of the study, the conduct or management of the study or the quality or safety of any IMP in the trial. Substantial amendments must be approved by the HRA, Ethics (REC) and the MHRA (for CTIMP studies).

- Non-substantial (minor); changes to the details of a trial that are administrative. Non-substantial amendments must be submitted to the HRA who may notify the REC.

It is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial, and to obtain all the required approvals.

This SOP applies to all substantial and non-substantial amendments.

Unless it is an Urgent Safety Measure (see R&D/S68) an amendment should only be implemented in the Trust once all approvals from the relevant review bodies have been received (HRA, REC and MHRA) – receipt of these approvals is checked and confirmed by R&D Research Governance staff.

4.2 Amendment categories

The HRA will assign a category to each amendment:

- Category A: An amendment to a research study that ALL participating NHS organisations are expected to consider.

- Category B: An amendment to a research study that only those participating NHS organisations affected by the amendment are expected to consider.

- Category C: An amendment to a research study that participating NHS organisations are not expected to consider.

This SOP applies to all categories of amendments.

4.3 Reviewing Amendments

As per R&D/S07, notification of amendments may be received from Research Governance, the Research Team, or directly from the Sponsor. Upon receipt of an amendment the Laboratory Research Team must review the amendment using the following steps:

1) At the earliest convenience, receipt of the amendment should be documented on columns A-C of the Amendment Log Spreadsheet. A member of the Laboratory Research Team must be assigned to review, accept, and implement or reject the amendment (column D).

2) Create a folder in the study specific file and save the amendment documents. This should be documented on column E of the Amendment Log Spreadsheet.

3) Review the amendment by documenting the changes that have been made and complete columns F and G on the Amendment Log Spreadsheet. If there is any aspect of the amendment that the team are unsure about, they should liaise directly with the Sponsor and PI.

4) Once all of the changes have been identified, it must be determined whether they impact on the Laboratory Research Service. This should be documented on column H of the Amendment Log Spreadsheet. The following details how amendments may impact on the Lab Research Team and how this determines whether they are approved, rejected or acknowledged (Section 4.4 details how approval, rejection or approval is confirmed and timelines for this process):

    - If there is no impact on the Laboratory Research Service, approval can be sent to Research Governance.

    - If the amendment does impact Laboratory Research e.g. there are additional samples to process, the individual reviewing the amendment should assess whether Laboratory Research have the capacity and capability to continue to support the study taking into account; cost implications, workload, other resource implications, practical aspects of processing, storing and shipping of study samples, and staff training requirements. Once assessed, either approval or rejection of the amendment may then be sent to Research Governance.

    - If the amendment requires support from other pathology disciplines, e.g. Histology, the Laboratory Research Team must inform the Head BMS from the discipline and obtain permission before approving or rejecting the amendment.

    - <u>For studies with research samples processed via standard care pathway:</u> if the amendment involves changes that will impact on the Main Laboratory service e.g. additional tests, more frequent tests, the Laboratory Research Team should:

        1. Confirm with the PI whether these tests are part of standard care for that group of patients. If they are, the Laboratory Research Team can inform Research Governance of their approval of the amendment.

        2. If these changes are outside of standard care, Research Governance, the PI, and the Research Team should be informed that there will be excess treatment costs associated with the amendment. The PI and Research Governance must come up with an arrangement to cover the excess costs and the Head BMS from the relevant pathology discipline must approve the amendment prior to the Laboratory Research Team issuing approval.

Some amendments (often Category C) do not require study-wide review and have no impact on the trust (or therefore Laboratory Research). These amendments still require an acknowledgement to be sent to Research Governance.

4.4 Confirmation of Acceptance, Rejection or Acknowledgement of Amendments

1) Confirmation of acceptance, rejection, or acknowledgement of amendments must be emailed to Research Governance for amendments with and without impact on Laboratory Research. The following points and timelines should be applied to this process:

   - If the amendment has no impact on the Laboratory Research Service, or the Laboratory Research Team have the capacity and capability to implement the amendment, Research Governance must be informed of their approval of the amendment within **35 days**.

   - If the Laboratory Research Team decided to reject the amendment, Research Governance must be informed within **35 days** of the notification of the amendment.

   - If more time is required to review the amendment Research Governance must be informed in order to ensure that the amendment is not automatically implemented after **35 days**.

   - If the Research Governance team do not hear anything within **35 days** of notification of the amendment, approval will be assumed, and an email of Continuing Capacity and Capability will be sent to the Sponsor.

   - For amendments that do not require study-wide review and have no impact on the trust, an acknowledgement should be sent the Research Governance.

2) The date that the approval, rejection or acknowledgement of an amendment was emailed to Research Governance should be documented column I on the Amendment Log Spreadsheet.

4.5 Local Implementation of Amendments

1) Once all local and regulatory approvals have been received, Research Governance will issue an email of Continuing Capacity and Capability. This should be documented on column J on the Amendment Log Spreadsheet. For studies that do not require a study-wide review this should also be documented in column J.

2) On receipt of an email confirming Continuing Capacity and Capability, the PI (or delegated other) should contact the Laboratory Research Team and agree a local implementation date for the amendment. This should be documented on column K of the Amendment Log Spreadsheet

3) On the agreed implementation date, a member of the research team should ensure that:

- New versions of relevant study documents are saved electronically in the appropriate section of the study folder and any old versions are moved into superseded folders (complete column L).

- New versions of relevant study documents are printed and filed in the Lab Research File and any old versions are superseded and filed in the appropriate section of the file (complete column M) or disposed of, when appropriate. Note: for Local and Standard Care Studies, no printouts of amendments are required (no Lab Research File kept for such studies).

- The amendment must be recorded in the 'Laboratory Amendment Log' in section 4 of the paper Laboratory Site File. Note: for Local and Standard Care Studies, there is no paper amendment log (no Lab Research File kept for such studies).

- All columns on the Amendment Log Spreadsheet should be completed. Column N can be used to document any comments relating to the amendment.

5 Related SOPs and Documents

R&D/S07 Implementing amendments for research studies NOT sponsored by the Trust

R&D/S74 Making amendments to Trust Sponsored Research studies

R&D/S75 R&D processing of amendments

R&D/S68 Urgent Safety Measures or Safety Concerns requiring a temporary or permanent halt to a study

R&D/F23 Laboratory Amendment Log