1. Introduction

This Standard Operating Procedure (SOP) details the University Hospitals of Leicester NHS Trust (UHL) procedures for managing amendments in research studies where the UHL is acting as the Host Organisation or Research Site.

It is recognised that from time to time approved documentation used in a research study requires amendment and in some cases that additional documents are required.

Some amendments require the Host organisation authorisation prior to implementation, but others simply require acknowledgement of the amendment.

2. Scope

This SOP applies to all individuals involved in research studies HOSTED by UHL and applies to ALL amendments for ALL studies.

3. Definitions

Essentially from a regulatory perspective there are two types of amendments. The type of amendment must be a decision made by the Sponsor.

- Substantial
- Non-Substantial

These are then categorised by the Sponsor prior to processing and category confirmation by the Health Research Authority (HRA). The categories are:

- **Category A:** Amendment to a research study that all participating NHS Organisations are expected to consider
- **Category B:** Amendment to a research study that only those participating NHS Organisations affected by the amendment are expected to consider
- **Category C:** Amendment to a research study that participating NHS Organisations are not expected to consider

4. Procedure

All amendments to any research documentation must be sent to the Research Team and copied to the R&I Office. The R&I Office will then assist the Research Teams to implement the amended documentation as required, and provide the relevant authorisation or acknowledgement for the amendment.

4.1)
All documentation relating to the proposed substantial amendment must be submitted to the Research Team and the R&I Office prior to implementation.

4.1.1)

All documentation relating to the proposed amendment must be submitted to the R&I Office by using the RIAdmin@uhl-tr.nhs.uk generic mail box.

Documentation required but not limited to must include:

- Email to sponsor confirming HRA Categorisation of Amendment
- Completed amendment tool (SA)
- Documentation approved by REC &/or HRA
- Regulatory approvals (REC, HRA, MHRA)
- All relevant approval confirmations (letters / emails)

Sponsors are encouraged to provide the research teams & R&I Office with initial documentation and confirmation of categorisation email from the HRA. This will allow relevant assessment of the amendment during the process of approval. Once the approved documents and confirmation of approval has been received, the amendment can then be implemented provided UHL has confirmed.

UHL as a site is required to confirm implementation of an approved amendment within 35 days of receipt of all approved documentation. If confirmation is possible within 35 days the amendment may then be implemented. There is no requirement to wait for the full 35 days.

If the UHL has not responded to the sponsor within 35 days with queries or to notify of a reason why an amendment cannot be implemented at the deadline, the sponsor may assume continuing permission (subject to other regulatory approvals).

4.1.2)
Support Departments Approval

During the assessment period, it is essential that the relevant support departments involved in the study are informed of the amendment. Where the amendment does not affect their specific role within the study, the amendment may simply be sent to them for their information only. Where an amendment has a direct effect on the role that they have, individual support department approval will be required prior to UHL confirmation of acceptance of the amendment. Where there are financial implications to the amendment, finance approval must also be sought.

4.1.3)
UHL Confirmation of Amendment

Once all relevant documentation, regulatory and support department approvals have all been received by the R&I Office, an email to confirm authorisation of the amendment will be sent. The email must be retained in the Investigator Site File.

4.2)
Substantial Amendment – Category B

ONLY when the amendment affects UHL, all documentation relating to the proposed amendment must be submitted to the R&I Office by using the RIAdmin@uhl-tr.nhs.uk generic mail box. When the amendment has no impact on UHL there is no need to submit for authorisation.

Documentation required but not limited to must include:

- Email to sponsor confirming HRA Categorisation of Amendment
- Completed amendment tool (SA)
- Documentation approved by REC &/or HRA
- All relevant approval confirmations (letters / emails) (REC, HRA MHRA)

Sponsors are encouraged to provide the research teams & R&I Office with initial documentation and confirmation of categorisation email from the HRA. This will allow relevant assessment of the amendment during the process of approval. Once the approved documents and confirmation of approval has been received, the amendment can then be implemented provided UHL has confirmed.

UHL as a site is required to confirm implementation of an approved amendment within 35 days of receipt of all approved documentation. If confirmation is possible within 35 days the amendment may then be implemented. There is no requirement to wait for the full 35 days.

If the UHL has not responded to the sponsor within 35 days with queries or to notify of a reason why an amendment cannot be implemented at the deadline, the sponsor may assume continuing permission (subject to other regulatory approvals).

4.2.1)
Support Departments Approval

During the assessment period, it is essential that the relevant support departments involved in the study are informed of the amendment. Where the amendment does not affect their specific role within the study, the amendment may simply be sent to them for their information only. Where an amendment has a direct effect on the role that they have, individual support department approval will be required prior to UHL confirmation of acceptance of the amendment. Where there are financial implications to the amendment, finance approval must also be sought.

4.2.2)
UHL Confirmation of Amendment

Once all relevant documentation, regulatory and support department approvals have all been received by the R&I Office, an email to confirm authorisation of the amendment will be sent. The email must be retained in the Investigator Site File.

4.3)
Substantial Amendment – Category C

All documentation relating to the proposed amendment must be submitted to the R&I Office by using the RIAdmin@uhl-tr.nhs.uk generic mail box. Where there is no impact on UHL or revisions to any documentation used by UHL there is no requirement to notify.

Receipt of the documentation will be acknowledged by email. There is no requirement for further authorisation prior to implementation of this category of amendment.

4.4)

Non-Substantial Amendments

All documentation relating to the proposed non-substantial amendment must be submitted to the Research Team and the R&I Office prior to implementation.

4.4.1)
All documentation relating to the proposed amendment must be submitted to the R&I Office by using the RIAdmin@uhl-tr.nhs.uk generic mail box.

Documentation required but not limited to must include:

- Email to sponsor confirming HRA Categorisation of Amendment
- Completed amendment tool both SA and NSA. (SA)
- Documentation approved by HRA
- All relevant approval confirmations (letters / emails)

Sponsors are encouraged to provide the research teams & R&I Office with initial documentation and confirmation of categorisation email from the HRA. This will allow relevant assessment of the amendment during the process of approval. Once the approved documents and confirmation of approval has been received, the amendment can then be implemented provided UHL has confirmed.

UHL as a site is required to confirm implementation of an approved amendment within 35 days of receipt of all approved documentation. If confirmation is possible within 35 days the amendment may then be implemented. There is no requirement to wait for the full 35 days.

If the UHL has not responded to the sponsor within 35 days with queries or to notify of a reason why an amendment cannot be implemented at the deadline, the sponsor may assume continuing permission (subject to other regulatory approvals).

4.4.2)
Support Departments Approval
During the assessment period, it is essential that the relevant support departments involved in the study are informed of the amendment. Where the amendment does not affect their specific role within the study, the amendment may simply be sent to them for their information only. Where an amendment has a direct effect on the role that they have, individual support department approval will be required prior to UHL confirmation of acceptance of the amendment. Where there are financial implications to the amendment, finance approval must also be sought.

4.4.3)
UHL Confirmation of Amendment
Once all relevant documentation, regulatory and support department approvals have all been received by the R&I Office, an email to confirm authorisation of the amendment will be sent. The email must be retained in the Investigator Site File.

4.5)

Non-Substantial Amendments – Category C

All documentation relating to the proposed amendment must be submitted to the R&I Office by using the RIAdmin@uhl-tr.nhs.uk generic mail box. Where there is no impact on UHL or revisions to any documentation used by UHL there is no requirement to notify.

Receipt of the documentation will be acknowledged by email. There is no requirement for further authorisation prior to implementation of this category of amendment.

5. Urgent Safety Measures

In cases where Urgent Safety Measures (USM) are required, it is acknowledged that is not always appropriate to wait until approval has been granted before implementation. In these cases, the amendment must be implemented immediately or as instructed by the Sponsor, then will be reviewed retrospectively once it has been submitted.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Sponsor representative	Confirm nature & category of amendment – Substantial, Non-Substantial, Category A,B or C or Urgent Safety Measures. Ensure all relevant documentation is received at the Site.
2	Principal Investigator	PI or research team	Review all relevant amendment documentation submitted by the Sponsor and assess for capacity and capability. Ensure R&I and all relevant support departments including finance have copies of all documentation

	Responsibility	Undertaken by	Activity
3	R&I	Study Support Officer	Assist research team with assessment and implementation. Provide email of authorisation following receipt of all relevant documentation.

7. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

8. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

9. Education and Training

None

10. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

11. Supporting Documents and Key References

None

12. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, Amendment, NSA, SA

13. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

14.

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This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 09/07/2021.

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
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February 2019	3	CM, LW	Consistency Check. Update to Logo
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