Standard Operating Procedure	Lancaster University

Title: Amendments to Lancaster University Sponsored Studies (non-CTIMP)

SOP Reference: HSCR-SOP006	**Date Effective From: 2025**
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Superseded SOP (version and date): NA	**Date of Next Review: 2027**

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Approved by:
(name and position)

Date:

Document History

Version	Date	Reasons for Change
V1.0	**20/05/2025**	**New Document**

1. Background

1.1. In line with the UK Policy Framework for Health and Social Care Research, all health and social care research within the remit of the Secretary of State for Health requires a formal sponsor. This includes studies involving NHS patients, their data or tissue, NHS staff, and the use of NHS facilities or resources. Similar requirements apply to research involving social care practitioners, clients, and associated resources.

1.2. The policy outlines that the Sponsor as the individual, organisation, or partnership that assumes overall responsibility for the initiation, management, and financing (or the arrangement thereof) of a research study. The sponsor must ensure that the study complies with all applicable regulatory and ethical standards throughout its duration, and that robust systems are in place for oversight.

1.3. An amendment refers to any change made to an approved research study after initial sponsor authorisation and ethical/regulatory approval has been granted.

1.4. Sponsors are required to have formal procedures for the evaluation and classification of amendments to ensure continued ethical and regulatory compliance and continued alignment to the universities risk appetite.

1.5. The Health Research Authority (HRA) and the National Research Ethics Service (including NHS Research Ethics Committees) also maintain processes for reviewing and approving amendments, where applicable.

1.6. Amendments are classified as either substantial or non-substantial, as determined by the sponsor and supported by the IRAS Amendment Tool.

- **Substantial amendments** include changes likely to impact:
    - The safety, physical or mental integrity of participants,
    - The scientific value of the research,
    - The conduct or management of the study.
- **Non-substantial amendments** do not affect the above factors but must still be documented and, in some cases, reported.

2. Purpose and Scope

2.1 This SOP outlines the procedure to be followed by chief Investigators and their delegated research teams at Lancaster University when preparing, submitting, and implementing amendments to research studies for which Lancaster University acts as the sponsor.

2.2 It aims to:

- Ensure researchers understand their responsibilities in submitting amendments for sponsor, regulatory and ethical review and approval;
- Ensure regulatory and ethical compliance are maintained, in accordance with ICH-Good Clinical Practice (GCP) and institutional standards, across all sponsored studies.
- Assess Lancaster Universities ongoing ability to act as sponsor for the study in light of changes.

3. Procedure

3.1 Preparation of Amendment Documentation

When an amendment is proposed, the Chief Investigator (CI) or an authorised delegate is responsible for compiling the following:

- The IRAS Amendment Tool,
- Any revised study documentation (with tracked changes),
- Any newly developed documents, clearly version-controlled and dated.

The format for non-substantial amendment references must be sequential from NSA001 onwards; for substantial amendments, the reference must be sequential from SA001 onwards. Where the research team are unsure, they may leave the reference empty, and this will be completed during the sponsor review procedure.

The sponsor representative and Head of Research Quality and Policy is the sole signatory, and research teams should not complete the authorisation fields on the amendment tool.

3.2 Classification and Categorisation

The IRAS Amendment Tool will determine whether the amendment is substantial or non-substantial and assign a category that will both dictate the required level of sponsor and regulator review required. Categories are:

- **Category A**: All participating NHS organisations are expected to review.
- **Category B**: Only affected NHS organisations are expected to review.
- **Category C**: No NHS organisations are required to review.
- **New Site**: Applies only to the newly added site.
- **Non-notifiable (N/A)**: NHS organisations are not expected to consider.

3.3 Submission for Sponsor Review

The CI or delegate must request sponsor authorisation prior to submission to regulatory bodies. Requests should be sent to the Clinical Research Governance Team and include:

- The completed IRAS Amendment Tool,
- Tracked and clean versions of all affected documents.

3.4 Sponsor Review and Authorisation

Upon receipt, the Clinical Research Governance Officer (CRGO) will review the documentation to ensure accuracy, completeness, and continued alignment with the sponsor's risk appetite. The studies initial risk assessment must also be revisited in case of change to the risk score.

- **Non-substantial amendments** will be authorised by the **CRGO on behalf of the sponsor representative** and returned to the research team for submission.
- **Substantial amendments** or those requiring further input will be subject to additional review by the **Health and Social Care Research Sponsorship Committee or a delegated member**. Final authorisation will then be provided by the **CRGO on behalf of the sponsor representative** once deemed suitable and returned to the research team for submission.

No further edits may be made once the amendment is authorised and locked for submission.

3.5 Submission to Regulatory Authorities

Once returned to the research team, authorised amendments must be submitted via the IRAS identity gateway area, which is separate to the main IRAS application system. This should be completed by the CI or delegated research team member, following the tailored instructions provided in the 'submission guidance' tab of the excel Amendment Tool. A link to the gateway can also be found under this tab.

3.6 Non-notifiable Amendments

These amendments are not submitted to regulatory bodies but must still be submitted and verified by the sponsor. Researchers can check if their amendment is non-notifiable by referring to section 4 of the completed amendment tool, under 'overall amendment type'. All non-notifiable amendments must be stored in the Trial Master File (TMF).

3.7 Implementation of amendments

The research team is responsible for notifying participating research sites of any submitted amendments. Implementation timelines depend on the amendment category:

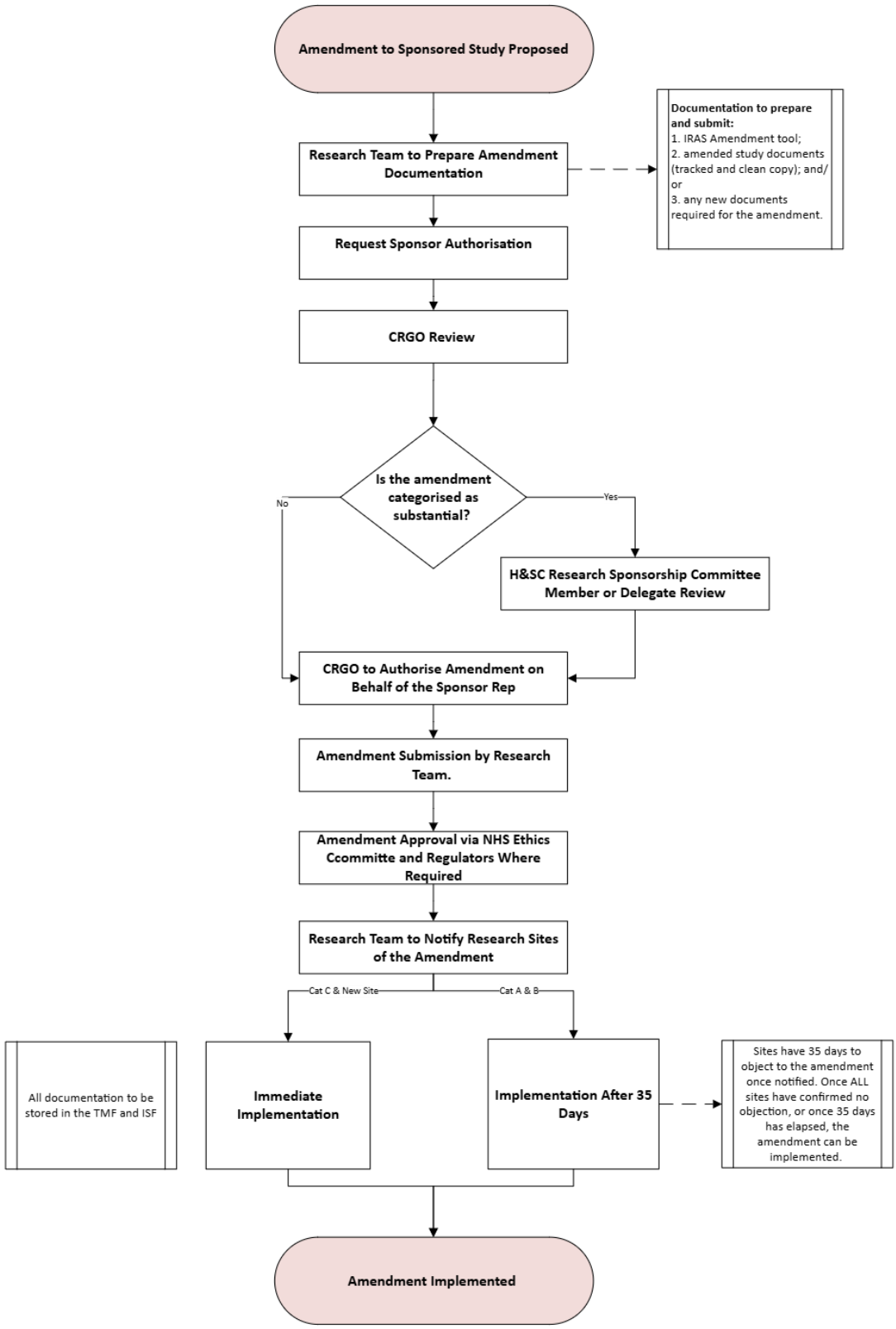
- **Category A or B**: Sites have up to 35 days to raise objections. If none are raised, the amendment may be implemented thereafter. If sites respond with no objection before the 35 days have elapsed, the amendment may be implemented.
- **Category C or New Site**: May be implemented immediately upon notification.

No amendment may be implemented prior to obtaining all necessary ethical and regulatory approvals.

3.8. Record Keeping

All relevant confirmation emails and approval documents must be filed in the TMF. Sites may also retain copies in their Investigator Site Files. The sponsor will maintain a comprehensive record of all authorised amendments.

4. Flow Chart


Amendment to Sponsored Study Proposed
Research Team to Prepare Amendment Documentation
Documentation to prepare and submit:
1. IRAS Amendment tool;
2. amended study documents (tracked and clean copy); and/or
3. any new documents required for the amendment.
Request Sponsor Authorisation
CRGO Review
Is the amendment categorised as substantial?
No
Yes
H&SC Research Sponsorship Committee Member or Delegate Review
CRGO to Authorise Amendment on Behalf of the Sponsor Rep
Amendment Submission by Research Team.
Amendment Approval via NHS Ethics Ccommitte and Regulators Where Required
Research Team to Notify Research Sites of the Amendment
Cat C & New Site
Cat A & B
All documentation to be stored in the TMF and ISF
Immediate Implementation
Implementation After 35 Days
Sites have 35 days to object to the amendment once notified. Once ALL sites have confirmed no objection, or once 35 days has elapsed, the amendment can be implemented.
Amendment Implemented