# SOP06 – Amendments to Research Sponsored by De Montfort University

1. **Introduction**

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within De Montfort University when completing the Sponsor Approval Process for amendments to research that has previously received formal approvals.

The outcome is that the Research Governance Office is able to confirm that DMU has conducted a revised Risk Assessment and is able to continue to act as research Sponsor.

1. **Scope**

This SOP applies to all research where DMU acts as sponsor in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

1. **Categories of Amendments**

Amendments are viewed as changes to any research documentation that has been reviewed and approved by regulatory authorities and the Sponsor.

There are two types of amendments:

• Substantial amendments

• Non-Substantial amendments

Guidance (<https://www.hra.nhs.uk/approvals-amendments/amending-approval/>) must be consulted when considering whether an amendment is substantial or non-substantial.

*It is important to note that ANY change to ANY documentation must be sent to the Sponsor before the changes are implemented, or submitted to regulatory authorities, except in case of Urgent Safety Measures.*

1. **Substantial Amendments**

It is the responsibility of the Sponsor to decide whether or not an amendment is substantial. In addition, the Sponsor must decide whether or not the amendment requires a favourable opinion from the Research Ethics Committee.

In addition to the REC, the Host Organisation R&D Office may also require submission of amendments prior to implementation at the NHS site. It is therefore essential that a review of the NHS R&D SOPs is undertaken for each site using the Green Light Sign-Off form (SOP03 Annex D).

All amendments must be sent to the Research Governance Office for sponsor review. All documentation to be amended along with relevant amendment forms must be included. The Research Governance Office will review the documentation and will formally confirm that the amendment is ‘substantial’ and will advise on the approvals required.

The Research Governance Office will review the amendment documentation, and will revise the initial Sponsor Risk Assessment form as necessary. This may require further review by the Research Office if the amendment affects the risk outcome in accordance with SOP05. If an amendment includes the addition of new sites or Third Parties, the relevant SOP05 will be implemented.

If necessary a face-to-face meeting with the Chief Investigator and / or study personnel will be requested to discuss the proposed amendment in detail prior to Sponsor Amendment Approval confirmation.

The Research Governance Office will complete the Sponsor Amendment Approval document during the review of amendment documentation. When the documentation review and revised risk assessment has been completed, and relevant action has been taken or is in progress to mitigate any additional risk identified, the Research Governance Office will confirm to the Chief Investigator the sponsor permission to submit the amendment to relevant regulatory authorities.

Sponsor amendment approval will be confirmed on receipt of documentary evidence that the relevant permissions, any additional contracts or agreements are in place, confirmation of indemnity and regulatory authority approvals have been received. The Green Light Sign-Off form (SOP05 Annex D) must be completed in the Sponsor file, along with copies of all relevant documentation. A sponsor amendment approval confirmation letter will be sent allowing implementation of the amendment to take place.

Multi-centre studies: In cases of Multi-centre studies, there is a requirement for each site to approve amendments prior to implementation of the amendment. It is the Chief Investigator’s responsibility to ensure that the RGO has received copies of relevant Trust R&D approval in order for the our approval to be given. The Chief Investigator must ensure that amendments are not implemented at sites prior to receipt of the Sponsor approval.

1. **Non-Substantial Amendments**

Where amendments are deemed to be Non-Substantial/Administrative/Minor in accordance with HRA guidance, the amendment may be submitted to the REC & NHS Trust R&D offices for Favourable Opinion/ Approval / acknowledgement as necessary ensuring that DMU as Sponsor is copied into any correspondence.

It is important to remember that the Sponsor must be sent a copy of any revised study documentation and details of changes in personnel during the lifecycle of a research study once approved.

1. **All other amendments**

All documentation not requiring HRA approval as a substantial or non-substantial amendment must be sent to the Research Governance Office for information purposes only before being implemented.

1. **Urgent Safety Measures**

In cases where Urgent Safety Measures (USM) are required, it is acknowledged that is not always appropriate to wait until sponsor authorisation has been granted. In these cases, the amendment will be reviewed retrospectively. See SOP07 Urgent Safety Measures.

The Sponsor must ensure that the REC is notified of the USM immediately, and in any event within 3 days, that such a measure has been taken, and the reasons why it has been taken.

1. **Non- Compliance**

Where it is identified that the processes detailed above have not been followed a Non-Compliance will be implemented at a minimum of a Major finding.

1. **Document Control**

|  |
| --- |
| **DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT** |
| **Author:** Douglas Gray | **Job Title:** Faculty Head of Research Ethics (HLS) |
| **Approved by:** University Research Ethics Committee | **Date Approved:** 14/04/2021 |
| **REVIEW RECORD** |
| **Date** | **Issue****Number** | **Reviewed By** | **Description of Changes (If Any)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **DISTRIBUTION RECORD:** |
| **Date** | **Name** | **Dept** | **Received** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |