UNIVERSITY OF LEICESTER

Research Governance Office Sponsorship

Standard Operating Procedures

Process for Sponsor Review and Approval of Modifications

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1.0 Introduction and Scope

This SOP details the procedures to be followed by Researchers and the Research Governance Office (RGO) for managing modifications to UoL Sponsored research (referred to as 'trial' hereafter).

This SOP describes the internal Sponsor process for requesting a review of proposed modifications and outlines how approval decisions are communicated and implemented. It details the steps investigators and study teams must follow when seeking Sponsor assessment, including documentation requirements, internal review pathways, and expectations for implementing the modification once authorised.

The outcome is that the RGO is able to confirm that the UoL has conducted a Sponsor review of the proposed modification, and where applicable, have undertaken/revised the Risk Assessment and Monitoring Plan, and is able to continue to act as the Sponsor.

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2.0 Overview of Modifications

Modifications are viewed as changes to any research documentation or arrangements that have previously been reviewed and approved by regulatory authorities and the Sponsor.

The requirements for submitting and implementing modifications to trials vary depending on the type of trial and the nature of the changes being proposed. Under the UK regulatory framework, modification categories, definitions, and approval routes differ across Clinical Trials of Investigational Medicinal Products (CTIMPs), medical device investigations, and non-CTIMP research. Likewise, the level of regulatory and ethics review required for a given change is determined by the specific impact of the modification on participant safety, scientific validity, trial conduct, and regulatory compliance.

Comprehensive and current guidance on modification types, categorisation, and submission requirements is maintained by the Medicines and Healthcare products Regulatory Agency (MHRA), and by the Health Research Authority (HRA) where applicable.

Because these requirements are externally defined and periodically updated, this SOP does not duplicate that guidance. Instead, trial teams must ensure they consult the relevant MHRA and HRA resources when preparing any modification.

Additional help and guidance can be accessed:

- HRA
- IRAS help
- Infonetica SharePoint pages (UoL log in required)
- Modification SharePoint webpages (UoL log in required)

When completed accurately, the HRA modification tool automatically categorises the proposed change and indicates which parties are required to review and approve it.

3.0 Version and Document Control for Modifications

The following version control should be used;

- Substantial Modifications = a change in version numbers to the next whole number (i.e., v1.3 will become v2.0, v4.0 will become v5.0)

- Non-Substantial Modifications = a change in version numbers to the next decimal number (i.e., v1.3 will become v1.4, v4.0 will become v4.1)

The dates of all the updated documents must match the date on the modification tool.

The footers and filenames must also be updated; we recommend the following format: Sponsor Ref (IRAS Number)_Doc Title_vX.X_DD-MM-YYYY (you can also add 'TRACKED CHANGED' (or 'TC') or 'CLEAN' to the end of the filename to make it easier to identify documents).

4.0 Process for Sponsor Review of Modification(s)

All modifications must be reviewed by the RGO and must not be submitted for external regulatory approvals without prior permission. The CI (or delegate) is responsible for ensuring the process detailed below is followed;

1. Draft a Modification Tool (downloaded here) and prepare documentation (i.e., new documents, or tracked and clean versions of already approved documents, evidence of funding (where applicable)). Researchers must not sign the declaration section of the Modification Tool.

   Draft costings must be submitted to, and approved by, the Pre-Award and Contracts (PAC) Team PRIOR to sharing with the funder for their approval, and PRIOR to the submission of the modification request.

   Costings must be shared with PAC via Worktribe.

2. Create a 'Modification Request Form' within Infonetica (guidance here), complete the information and upload the documents (from Step 1, above) prior to submitting the form and documents for RGO review.

3. RGO will review the modification and may request additional documents, and/or changes via emails generated by Infonetica and/or the reviewer. Where a modification affects original trial information within Infonetica (e.g., sample size, change in end date, changes to the storage of samples and/or data etc.), the RGO will request that the CI (or delegate) updates the main

project form.
Where applicable, the following activities must also occur:

a. **Risk Assessment and/or Monitoring Plan updated**. *If additional risk(s) are identified and/or the overall risk outcome is affected, relevant action must be taken to mitigate such risk(s). SOP S-1003 Sponsor Risk Assessment will apply.*
b. **Service providers notified of the modification and provided with updated documentation**. *An impact assessment should be performed and any changes to the provision of service must be documented. SOP S-1037 will apply.*
c. **Case Report Forms (CRFs) and Database updated**. *It is essential that any CRFs/Electronic Data Capture (EDC) systems/clinical database updates linked to a protocol modification are built, tested, and released in sync with the modification's implementation so that CRFs and electronic data capture always reflect the current protocol and ensure accurate, compliant data collection. An impact assessment of the modification on the database should be performed.*

4. Once all requests have been actioned, or there are no further changes required, the RGO will sign off the Modification Tool. A locked PDF copy will be emailed to the trial manager or relevant study contact as applicable. Notification of permission to submit for regulatory notification/approval will be issued via Infonetica.

Detailed instructions about Sponsor Green Light and the implementation of the modification will be included in the emails generated by Infonetica during the review process. Researchers must read these carefully and in full because Sponsor Green Light will be issued at different times depending upon the type of modification being requested. See Step 7 below for an overview.

5. The modification should be submitted using the relevant IRAS submission portal* and the modification shared with participating research locations using the standardised email templates as per the guidance in the Infonetica email. For National Institute for Health and Care Research (NIHR) Research Delivery Network (RDN) portfolio adopted trials, engage with the RDN to inform them of the modification and ensure that the EDGE and CPMS records are updated accordingly. Any other relevant personnel e.g. vendors/service providers should be notified where relevant.
6. Await feedback and/or external regulatory approvals and NHS Trust Confirmation of Capacity and Capability (if applicable)
7. Modification Implementation:
    a. For all modifications to CTIMPs and Medical Device Trials, the CI (or delegate) must create a '**Modification Sponsor Green Light (SGL)**' request form within Infonetica.
    b. For new site(s), the CI (or delegate) must create a '**Multi-Centre Site SGL**' request form within Infonetica. The process must be repeated per research location added via an amendment.**

The CI or delegate must complete the required information, and upload the relevant documents, prior to submitting the request for RGO review. The RGO will review the request ensuring all the relevant approvals/permissions/actions (e.g. database/risk assessment/monitoring plan updates) have been received/completed before SGL for research location will be issued via Infonetica.

   c. For all other types of modifications, in accordance with the guidance on the implementation of modifications for projects conducted in the NHS/HSC Sponsor Green Light will be issued along with the email/letter generated during Step 4 above.

8. The Sponsor Green Light email must be retained in the Trial Master File and Investigator Site File, along with copies of all relevant documentation and correspondence associated with the modification and its approvals.
9. Appropriate document control must be actioned following the modification and research staff at participating research locations must be trained in the modification accordingly.
10. The CI (or delegate) is responsible for ensuring that modifications are implemented appropriately and do not occur prior to the appropriate approvals being in place.

*If the MHRA need to be notified of the modification a copy of the locked modification tool and supporting documents should be submitted to the MHRA. If a trial was set up using the 'Combined Review' process, the delegate should prepare and submit the application using the new part of IRAS. If the trial was set up using the old part of IRAS, then the modification will need to be submitted via MHRA submissions.

Further guidance on submitting an application to the MHRA and supporting documentation which is required is available via from here: https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#amending-your-trial-protocol-or-other-documentation

**The following SOPs will apply; S-1025 Sponsor Green Light Process and S-1033 Process for assessing site feasibility.

The CI/PI must ensure that modifications are not implemented at research locations prior to the appropriate approvals and/or permissions being granted.

5.0 End Date Extensions

5.1 Useful definitions

Study end date:
The planned study end date is the date listed in section A69 of the IRAS form, or the date most recently approved via a modification.

Grant End date:
The grant end date is the end date listed on the grant award letter or contract.

Funded extension:
An extension is considered 'funded' if additional funding will be provided to support the extension.

Where additional funding is required, including from a new source, evidence of the agreed additional funds and the new duration within which the funds can be used must be provided.

No cost extension:
An extension is considered 'no cost' when additional funding will not be provided. In this case, evidence must be provided by the head of department/supervisor/departmental finance officer (as appropriate) to confirm that there are sufficient funds remaining to support the extension.

Confirmation of extension:
Where a study has been externally funded, agreement for the extension to the study and or grant end date must be obtained from the funder. An email or letter confirming the extension will suffice.

Where a study has been internally funded, agreement for the extension to the study end date must be obtained from the head of department/supervisor (as appropriate). An email or letter confirming the extension will suffice.

Worktribe:
Worktribe is a software system that is used to track funding from grants and associated contracting. Where a study has been funded by a grant, and where an extension will affect the end date of a grant, the Worktribe record needs to be updated.

PAC Team:
Pre-award and Contracts Team; who can be contacted for any queries relating to Worktribe, contracts, grants and finances: clspac@le.ac.uk

If you are unsure of what evidence/approvals you require please contact rgosponsor@le.ac.uk.

5.2 Process for extending a trial

The table below should be followed to confirm the steps you need to take.

	Externally funded trial		Internally funded trials	
	Funded Extension	No cost extension	Funded Extension	No cost extension
Log the relevant request in Worktribe	✓ Create a supplement request in Worktribe	✓ Create an extension request	N/A	N/A
Obtain evidence of the additional funding	✓ Share with PAC* and RGO**	N/A	✓ Share with RGO**	N/A

Obtain agreement of the end date extension from the funder	✓ Share with PAC* and RGO**	✓ Share with PAC* and RGO**	N/A	N/A
Obtain confirmation from Head of School/Supervisor/ Finance Officer that sufficient funds remain	N/A	✓ Share with RGO**	N/A	✓ Share with RGO**
Obtain agreement for the extension from Head of School/Supervisor/ Finance Officer that sufficient funds remain	N/A	N/A	✓ Share with RGO**	✓ Share with RGO**
Confirm the trial end date has been updated in Worktribe	✓ Share with RGO**	✓ Share with RGO**	N/A	N/A
Submit the completed modification tool and **all relevant supporting** documents to the RGO via Infonetica	✓	✓	✓	✓

*Pre-award and Contracts Team; please contact this team for any queries relating to Worktribe clspac@le.ac.uk
**Research Governance Office; please contact this team for all other queries relating to trial extensions rgosponsor@le.ac.uk

6.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	5.0	• Removal of Office address • Change of terminology throughout from 'amendments' to 'modifications' • Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations • Removal of process for non-Infonetica projects because this is obsolete • Removal of modification type definitions – replaced with links to regulatory websites to avoid providing out of date information and to improve the accessibility of complex information. • Removal of appendices. These will now become internal working documents. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive