



UNIVERSITY OF
LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures

SOP S-1018 UoL

Process for Sponsor Review and Approval of Amendments to UoL Sponsored Studies

Version 4.0 January 2024

Office Base
Research Governance Office
University of Leicester
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Effective Date: January 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction and Scope

This SOP details the procedures to be followed by Researchers and the Research Governance Office (RGO) for managing amendments to UoL Sponsored research.

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

In cases where amendments are as a direct result of Urgent Safety Measures (USMs), the approval can be obtained retrospectively. USMs are covered in SOP S-1029.

2.0 Definitions

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

There are several different 'amendment types' and 'amendment categories'. Amendment types are broadly defined below but often fall into one of two main types; 'substantial' and 'non-substantial'. An amendment's category is separate from whether it is substantial or non-substantial. The category confirms whether the amendment has delivery implications for all, some, or none of the participating organisations.

The table at the bottom of the amendment tool must be referred to for details on the overall 'amendment type' and 'amendment category'. Help can be found on the [IRAS webpages](#).

2.1 Substantial Amendments

A substantial amendment is a change that is likely to have a significant impact on:

- The safety or physical or mental integrity of the subjects, or
- The scientific value of the study, or
- The quality or safety or any Investigational Medicinal Product (IMP) used in the study, or
- The conduct or management of the study

Examples of substantial amendments can be found on the [HRA website](#).

2.2 Non-Substantial Amendments

Non-Substantial amendments can be defined as amendments that do not have any significant implications to:

- the conduct of the research
- the participants of the research
- scientific value
- management

Examples of non-substantial amendments can be found on the [HRA website](#).

2.3 Other Amendment Types

Other amendments may include 'no study-wide review (NSWR)', 'non-notifiable' amendments, or the addition of new sites.

3.0 Version and Document Control for Amendments

The following version control should be used;

- Substantial Amendments = 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 Amendments = 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 amended documents must match and must match the date on the amendment tool.

The footers and filenames must match; 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 Amendments Submitted via Email (applies to amendments submitted to the RGO before the 15th January 2024)

All amendments must be reviewed by the RGO and must not be submitted for external regulatory approvals without prior permission.

1. Draft an Amendment 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 Amendment Tool.**
2. Email the amendment tool and amendment documents (from Step 1, above) to rgosponsor@le.ac.uk for RGO review.
3. Additional documents, and/or changes may be requested during the review process.
4. The RGO will sign off the Amendment Tool (a copy will be emailed to you) and confirm that the amendment can be submitted for external regulatory approvals.
5. Submit the amendment using the IRAS online submission portal* and [share the amendment with participating sites](#) following the relevant instructions and using the standardised email templates.
6. Await feedback and/or external regulatory approvals to be issued.
7. The RGO will complete Appendix 1 Amendment Sponsor Green Light Checklist and issue Sponsor Green Light/Sponsor Acknowledgement (as appropriate and in accordance with the HRA/IRAS guidance).

*If the MHRA need to be notified of the amendment a copy of the locked amendment tool and supporting documents should be submitted to the MHRA. If your trial was set up using the 'Combined Review' process, you should prepare and submit your application using the new part of IRAS. If your trial was set up using the old part of IRAS then the amendment 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 CI must ensure that amendments are not implemented at sites prior to the appropriate approvals and/or permissions being granted.

8. The Sponsor Green Light or Sponsor Acknowledgement email must be retained in the Trial Master File/Investigator Site File, along with copies of all relevant documentation and correspondence associated with the amendment and its approvals
9. Where applicable, the Risk Assessment and/or Monitoring Plan will be 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.
10. Researchers must ensure that proper document control is actioned following the amendment and that research staff at participating sites are trained in the amendment accordingly.

5.0 Process for Amendments Submitted via Infonetica (applies 15th January 2024 onwards)

All amendments must be reviewed by the RGO and must not be submitted for external regulatory approvals without prior permission.

1. Draft an Amendment 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 Amendment Tool.**
2. Create an 'Amendment Request Form' within Infonetica, complete the information and upload the amendment documents (from Step 1, above) prior to submitting the form and documents for RGO review.
3. Additional documents, and/or changes may be requested. Refer to the instructions in the emails generated by Infonetica during the review process.
4. The RGO will sign off the Amendment Tool (a copy will be emailed to you) and confirm that the amendment can be submitted for external regulatory approvals.

Detailed instructions about Sponsor Green Light and the implementation of the amendment 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 amendment being requested. See Step 7 below for an overview.

5. Submit the amendment using the IRAS online submission portal and [share the amendment with participating sites](#) following the relevant instructions and using the standardised email templates.
6. Await feedback and/or external regulatory approvals to be issued.
7. Amendment Implementation:
 - a. For all amendments to CTIMPs and Medical Device Trials (and/or amendments that affect the overall risk outcome of a project), the CI (or delegate) must create an '**Amendment SGL**' request form within Infonetica, complete the information and upload the relevant documents prior to submitting the request for RGO review. RGO will review the request and will grant Sponsor Green Light for the amendment to be implemented via Infonetica.
 - b. For new site(s) amendments, the CI (or delegate) must create a '**Multi-Centre Site SGL**' request form within Infonetica once all relevant regulatory approvals and Confirmation of Capacity and Capability (or equivalent) have been issued. Complete the information and upload the relevant documents prior to submitting the request for RGO review. RGO will review the request and will grant Sponsor Green Light for the site via Infonetica. This must be done per each new site. The following SOPs will apply; S-1025 Sponsor Green Light Process and S-1033 Process for assessing site feasibility.

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

The CI must ensure that amendments are not implemented at sites prior to the appropriate approvals and/or permissions being granted.

8. Where an amendment affects original project 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.
9. If applicable, the Risk Assessment and/or Monitoring Plan will be 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.
10. Evidence of Sponsor Green Light must be retained in the Trial Master File/Investigator Site File, along with copies of all relevant documentation and correspondence associated with the amendment and its approvals.
11. The CI (or delegate) must ensure proper document control is actioned following the amendment, and that research staff at participating sites are trained in the amendment accordingly. Please refer to Section 3 (above) for guidance on document control.

Additional help and guidance can be accessed:

HRA: <https://www.hra.nhs.uk/approvals-amendments/amending-approval/>

IRAS help: <https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx>

Appendix 2 'How to Complete the Amendment Tool'

Infonetica SharePoint pages (UoL log in required)

6.0 End Date Extensions

6.1 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 previous amendment.

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 has been provided, 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/departamental 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. An email or letter confirming the extension will suffice.

Worktribe:

Worktribe is a software system that is used to track funding from grants. 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:

Post Award and Contracts Team; who can be contacted for any queries relating to Worktribe, contracts, grants and finances: clsspac@le.ac.uk

6.2 Other useful information

Sample analysis

The HRA have recently changed their guidance regarding sample analysis. Sample analysis must now be completed **prior to** a study being declared closed.

In most cases this change will not affect the grant end date, but will affect the study end date. Where the grant end date is not affected, a request to extend the study via Worktribe and correspondence with the Post Award and Contracts Team is not required. Instead, a request to extend to the study for the purpose of sample analysis must be submitted to the research governance office via Infonetica. No further funding evidence/extension approval is required. Please refer to our guidance on submitting an amendment.

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

6.3 Process for extending a study

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

	Externally funded studies		Internally funded studies	
	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 study end date has been updated in Worktribe	✓ Share with RGO**	✓ Share with RGO**	N/A	N/A
Submit the completed amendment tool and all relevant supporting documents to the RGO via Infonetica	✓	✓	✓	✓

*Post Award and Contracts Team; please contact this team for any queries relating to Worktribe clsspac@le.ac.uk

**Research Governance Office; please contact this team for all other queries relating to study extensions rgosponsor@le.ac.uk


7.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or their delegate	Confirm nature of amendment – Substantial, Non-Substantial, All other amendments or Urgent Safety Measures.
Chief Investigator	Chief Investigator or their delegate	Ensure all relevant amendment documentation is submitted to the Sponsor for review and authorisation.
Sponsor	Head of Research Governance or their delegate	Liaise with the Chief Investigator (or their delegate), during review of amendment documentation
Sponsor	Head of Research Governance or their delegate	Confirm authorisation to Chief Investigator (or their delegate) giving permission to submit to regulatory authorities
Sponsor	Head of Research Governance or their delegate	Complete and issue the Sponsor Green Light/Sponsor Acknowledgement for the implementation of the amendment.

Responsibility	Undertaken by	Activity
Sponsor, Chief Investigator or their delegate, Principal Investigator or their delegate	Head of Research Governance or their delegate and Chief Investigator or their delegate, Principal Investigator or their delegate	Ensure no implementation of amended documentation commences prior to appropriate approvals being in place.

8.0 Review Record

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	19/01/2024

9.0 Development and approval Record for this document

This table is used to track the changes made on revised/reviewed versions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	UoL RSMOG	SOP reviewed and revised to incorporate changes to logos, departmental titles and minor administrative changes to text, dates / footer. Also a Scope section added to document. Addition of Loughborough University to front page
Oct 2016	3	Diane Delahooke	Updated logo and reference made to HRA.
Sept 2021	3.1	Cat Taylor	Administrative changes
January 2024	4.0	Cat Taylor	Administrative changes Correction to SOP reference for Urgent Safety Measures Major updates to wording to clarify the amendment process following the introduction of Infonetica. Additional guidance on the process to follow when extending a study SOP 1018 and 1026 have been combined to prevent repetition. SOP 1026 will become obsolete upon the ratification of this SOP.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
			Addition of 2 appendices adapted from obsolete SOP 1026. Appendix 1 – Amendment Sponsor Green Light Checklist Appendix 2 – How to complete the amendment tool