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| **SOP009 Study Amendments for LJMU Sponsored Clinical Research** |
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| **Relevant to:** | *Staff and students conducting clinical research* |
| **Approved by:**  |  |
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| **Date introduced:** |  |
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| **Next Review Date:** |  |
| **RELEVANT DOCUMENTS** |
|  |
| **RELATED POLICIES & DOCUMENTS** |

This SOP needs to be a useful resource for investigators –please contact sponsor@ljmu.ac.uk with any suggestions for improvements.

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# Introduction

This document significantly replicates the procedures produced by the University of Liverpool, with changes made to encompass LJMU requirements. This is to facilitate research governance procedures in collaboration with the Liverpool Health Partners.

Amendments are changes made to a research project after approval from a review body has been given. To make an amendment, the CI will need to determine whether they need to notify the review bodies from whom approvals have been received. The amendments help section in the Integrated Research Application System (IRAS) provides information on whether a review body needs to be notified and if so, in what capacity and detailed instructions on submission of amendments.

## Definitions of amendments

An amendment to a research study can be either [**substantial** or **non-substantial**](https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/)**.**

Examples of substantial amendments:

* changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value;
* changes to the procedures undertaken by participants;
* changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
* significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
* a change of sponsor(s) or sponsor’s legal representative;
* appointment of a new chief investigator
* a change to the insurance or indemnity arrangements for the study;
* inclusion of a new trial site (not listed in the original application) in a CTIMP;
* appointment of a new principal investigator at a trial site in a CTIMP;
* temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
* a change to the definition of the end of the study;
* any other significant change to the protocol or the terms of the REC application.

Examples of non-substantial amendments:

* minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
* updates of the investigator’s brochure (unless there is a change to the risk/benefit assessment for the trial);
* changes to the chief investigator’s research team
* changes to the research team at particular trial sites (other than appointment of a new principal investigator in a CTIMP);
* changes in funding arrangements;
* changes in the documentation used by the research team for recording study data;
* changes in the logistical arrangements for storing or transporting samples;
* inclusion of new sites and investigators in studies other than CTIMPs;
* extension of the study beyond the period specified in the application form.

Changes to contact details for the sponsor (or the sponsor’s representative), chief investigator or other study staff are minor amendments but should be notified to the [REC that approved the original application](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/)

# Scope of Procedure

This standard operating procedure (SOP) describes:

* The procedure for making amendments to the protocol and any other essential study documentation.
* The procedure for gaining LJMU approval for LJMU sponsored clinical research studies.
* The notification process to REC, HRA, and other regulatory bodies.

For the purpose of this SOP, any reference to clinical research does not include studies defined as Clinical Trials of an Investigational Medicinal Product (CTIMP). Once established, LJMU sponsorship of a CTIMP will follow procedures for CTIMPs published by the Liverpool Health Partners or by LJMU REG.

# Procedure

## Who

This SOP is aimed at Chief Investigators (CI), students, trial coordinators and other members of University Staff involved in processing amendment and obtaining University, ethical, and regulatory approvals.

The SOP is also aimed at staff within LJMU Research Ethics and Governance (REG) who are involved in the review process of study amendments for LJMU Sponsored clinical research studies.

## When

This SOP should be referred to when making a substantial or non-substantial amendment to a LJMU Sponsored clinical research study.

## Substantial amendments

Prior to submission to external review bodies, the CI is required to notify the Sponsor [LJMU REG within LJMU Research Innovation Services (RIS)] of the proposed amendment, in order that the amendment be reviewed and assessed for suitability and substantiality and a decision made on the appropriate external review bodies to which it must be submitted. Where a study is Co-Sponsored with an NHS Trust LJMU will require confirmation of NHS Co- Sponsor review and approval prior to submission to external review bodies.

LJMU REG retain overall responsibility for reviewing the amendment retain overall responsibility for reviewing and approving amendments, however the function of review is undertaken by the LJMU Research Governance Manager.

Substantial amendments must be submitted to the REC that approved the research (either NHS REC or University Ethics), and the HRA (for HRA approved research). Submission of the amendment to other regulatory bodies may also be required depending on the initial approvals received.

For studies originally approved by an NHS REC, the notification of a proposed substantial amendment should be submitted using the “Notification of Substantial Amendment Form” in IRAS to generate a PDF form for your amendment. The PDF should then be emailed to LJMU REG and any co-sponsors. Once sponsor and co-sponsor approval has been confirmed by email, the CI should email the Sponsor approved PDF to the REC that approved the original application. REC staff will validate the amendment and categorise it if necessary. A validation letter with any categorisation will then be sent to the CI. At this stage, applicants should notify sites of the amendments and their categories. Further information on categorisation is available on IRAS.

The REC will review the amendment. There are three possible outcomes:

* Unfavourable opinion – The CI will need to return to the start of the process and resubmit
* Favourable opinion no further review from HRA required - applicants should communicate this to sites (both the research team and the R&D office), and the local CRN. If any amendments are category A or B, sites have 35 days to raise any objections, after which if no objections have been raised, the amendment can be implemented. Category C amendments can be implemented immediately.
* Favourable opinion further assessment needed - applicants will receive an email following further evaluation, after which the same process of notification as above should be followed.

## Non Substantial Amendments

Non substantial amendments should be emailed to LJMU REG using this [template](https://www.hra.nhs.uk/documents/1327/notification-non-substantialminor-amendmentss-nhs-studies.docx). Once approved the CI should email the non substantial amendment to hra.amendments@nhs.net.

The CI will not get a validation email but will receive a categorisation email. There are two possible outcomes:

* **HRA Approval for the amendment confirmed**
* **HRA Approval for the amendment pending**

In both cases, applicants should communicate this outcome to sites, along with the amendment application that was submitted. This should be sent to both the site research team and the R&D office, and the local CRN. If any amendments are [category A or B](http://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx), sites have 35 days to raise any objections, after which if no objections have been raised, the amendment can be implemented. [Category C amendments](http://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx) can be implemented immediately.

Where a HRA review is required, the HRA will review the amendment and issue HRA Approval of the amendment. Applicants should then notify sites of the outcome and provide the final approved documents.

## Implementing amendments at NHS organisations in England

The HRA have produced a series of email templates to support CIs when notifying NHS organisations in England of an amendment and to confirm when an amendment can be implemented.

The use of these email templates are optional, however the HRA believe their contents will allow sponsors to provide NHS organisations with the information they need to enable amendments to be implemented. The templates can be found below:

* [Category A or B site notification email template where HRA Approval is pending at categorisation](https://www.hra.nhs.uk/documents/1320/Template_email_to_share_category_A_or_B_amendment_-_approvals_are_outstanding.docx)
* [Category A or B site notification email, where HRA Approval is issued at categorisation](https://www.hra.nhs.uk/documents/1322/Template_email_to_share_category_A_or_B_amendment_-_approvals_in_place.docx)
* [Category C site notification email](https://www.hra.nhs.uk/documents/1326/Template_email_to_share_category_C_amendment_docs_with_sites.docx)
* [Amendment implementation email](https://www.hra.nhs.uk/documents/1319/Template_email_to_confirm_implementation_of_an_amendment.docx)

# Abbreviations

**CI** Chief Investigator

**CTIMP** Clinical Trial of Investigational Medicinal Product

**IRAS** Integrated Research Application System

**HRA** Health Research Authority

**REC** Research Ethics Committee

**PI** Principle Investigator

**REG** Research Ethics and Governance

# Associated Documents and References

HRA information on amendments - <https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/>

HRA Guidance <http://www.hra.nhs.uk/research-community/during-your-research-> project/amendments/

NHS RECs - https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/

UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017) <http://beta.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-> framework-health-social-care-research/

# Monitoring and Audit

Compliance with this SOP will be audited periodically as part of the LJMU REG audit plan.

# Change History

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| Version No. | Effective date | Significant changes  | Previous version No. |
| 1.0 | See page 1 | This is the first version of this SOP | n/a |