

Guidance Note for Submitting Amendments

TYPE OF AMENDMENT

Amendments are changes to studies that have already received a favourable decision from the Ethics Review Sub-Committee. The type of amendment required will depend on the nature of the changes being made. See the list below to determine which amendment type is required. If you are unsure contact LEON@lboro.ac.uk for guidance. Amendment requests must be submitted before changes are implemented, they cannot be approved retrospectively.

Before submitting minor amendments you should update the form if necessary. If you see the link below at the top of the form, please select 'update'.

Note: There is a newer version of the project. [Update](#)

Changes not requiring submission of amendment:

- Spelling corrections
- Formatting changes
- Removal of measures or questionnaires
- Changes to wording for clarification which do not change the study design
- Confirmation of insurance
- Changes to start date
- Removal of investigators
- Removal of incentive

Minor amendments (see below for submission details)

- Changes to end date
- Addition of investigators
- Change of responsible investigator/project supervisor for taught student projects (add as investigator)
- Inclusion or increase to incentive
- Addition of new sites or locations for the study where these do not increase the risks
- Reduction or minor increase in number, frequency or volume of bodily samples collected
- Reduction to frequency or duration of exercise/physical activity undertaken
- Addition of questionnaires where these are still relevant to the initial submission.
- Changes which would alter the responses to Section B of the initial submission
- Changes to age range of participants.
- Changing type of measure e.g. changing from interviews to focus groups where this is still in line with the initial submission.
- Minor change to participant group e.g. from Loughborough students to UK students.

Substantial amendments (see below for submission details)

- Substantial changes to study design
- Change of responsible investigator for PhD or Staff Projects
- Changes which would alter the responses to Section A of the initial submission
- Change to type of exercise/physical activity undertaken
- Increase to frequency or duration of exercise/physical activity undertaken

- Substantial increase in number, frequency or volume of bodily samples collected
- Changes to consent processes
- Change of location where this increases the risks e.g. to include travel to a country classed as high risk
- Changes to participant groups that would include vulnerable participants or increase the risk to participants.

[Staff only: For Generic Protocol amendments use the Generic Protocol Amendment Form.]

SUBSTANTIAL AMENDMENTS


For Substantial Amendments please contact the administrators at LEON@lboro.ac.uk. The original Ethics Review Form will be unlocked by the administrators so that it can be updated. Once updated the revised form should be submitted by requesting the relevant signatures. School signatures will be required for substantial changes. Substantial amendments are considered as new proposals and will follow the appropriate review process.

MINOR AMENDMENTS

For Minor Amendments you should submit the Minor Amendment Form through LEON. Details are given below.

1. CREATE AMENDMENT FORM:

From your Work Area in LEON you should select the title of the project that you need to change.

- Select 'Create Sub-form'  on the left-hand side and select 'Amendment (MINOR)' from the drop-down list.

2. COMPLETE THE AMENDMENT FORM:

Add details of your amendment request to the amendment form.

- Part One of the form 'Study Details' will be prepopulated from the original submission – please use this to ensure that you have selected the correct study to amend.
- Part Two of the form should be completed to indicate the requested amendments.
- Select the type of amendment and complete the relevant details.

3. SIGN AMENDMENT:


Once completed the form should be signed by the responsible investigator. If the responsible investigator is completing the amendment form, then select 'sign'. If you are not the responsible investigator then select 'request' and add the responsible investigators email address. For students the form should be signed by your project supervisor.

- **Studies which involves changes to the collection of Human Tissue Act Relevant material will also require approval from the relevant Schools. You should also send a signature request to the relevant contact from the list provided.**

4. SUBMISSION:

Once the relevant signatures are obtained the form will automatically be submitted. You will receive confirmation of submission by email. A decision will be sent to you by the Sub-Committee regarding the amendment once it has been reviewed.

5. **VIEW AMENDMENTS:**

To view amendments to studies, you should select the study from your Work Area and then select 'project' . This will take you to the 'Project Tree' which lists previous amendments.

- You can view details by clicking on the amendment in the list.