

Amendments triage system

In line with UCL Research Ethics guidance, amendments are triaged to identify the substantiveness of the changes to the research.

Minor amendments require a review by the Chair of the Research Ethics Committee, only.

Substantive amendments, however, need to undergo a full review, which involves two IOE reviewers independently assessing the ethical considerations of the research against a checklist.

Substantial amendments requiring a full ethics review

Changes to the design or methodology of the study, or to background information likely to have a significant impact on the ethical implications of the research.

- Changes to procedures undertaken by the participants to contribute to the research.
- Changes likely to have significant impact on the safety or physical or mental integrity of participants and/or researchers, or on the risk/benefit assessment for the study.
- Significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation.
- Change of sponsors and/or funders.
- Significant increase in participant numbers to be approached to take part.
- Addition of new study sites overseas and in the UK.
- Appointment of a new principal investigator.
- Any other significant change to the protocol or the terms of the ethics application (e.g., inclusion of incentives, change of software packages, change in data collection sources, change of social media platforms, change to opt-in/opt-out consent).

Minor amendments requiring review by the Chair of the REC

- Straight-forward extensions of the data collection period or project end date with no other changes to the study.
- Reversal of amendments to return to previously approved study details.
- All other changes to the design or methodology of the study, or to background information not likely to have a significant impact on the ethical implications of the research