Amendments - Guidance

Amendments are changes made to a research project after ethical approval has been given. Amendments should be submitted if significant changes are made to the design or implementation of the project, but which are not expected to affect the risks of the project.

Amendments

Examples of changes that would constitute amendments would include:

- An extension to the end date of a project
- Changes to the number of participants or means by which they are to be recruited
- An extension to more or different groups of participants, but where the level of vulnerability does not change, e.g. not-vulnerable to not-vulnerable, or vulnerable for reason A to vulnerable for reason A
- Changes to the procedures undertaken by participants, but which are not expected to affect the level of risk
- Inclusion of a new research locations, which are not expected to affect the level of risk
- Significant changes to study documentation, such as participant information sheets or consent forms

These amendments can be submitted using the Amendments tab of the original application on the Converis system.

Too substantial to be an amendment

Changes that are too major to constitute amendments would include:

- A major redesign of the project and particularly the intended methods of data collection
- Changes that are likely to have an effect on the level of physical or mental risk on the participants and/or researcher(s), e.g. more stress, exertion, provision of different substances, different doses, a potentially more risky research location etc.
- An extension to more or different groups of participants, but where the level of vulnerability does change, e.g. not-vulnerable to vulnerable, or vulnerable for reason A to vulnerable for reason B

In these instances, a new application would be required. However the first application can be referenced (using its ER number) in the new application or, where appropriate, the initial application can be cloned and then modified.

Too minor to be an amendment

Changes that are too minor to constitute amendments would include:

- Minor changes to the study documentation, e.g. correcting errors, updating contact points, minor clarifications
- Changes to the research team or funding arrangements

In these instances no additional ethical clearance is necessary and the research can continue uninterrupted.

IRAS applications

Where ethical approval has been obtained through IRAS, please follow the HRA amendments procedures instead: https://www.hra.nhs.uk/approvals-amendments/amending-approval/

Phased applications

Phased applications are different to amendments in that phased applications separate out different components of a single project, and seek separate approval for these sequentially. This is perhaps when the results of one stage will determine the design of a later one, or where methods of data collection will vary very substantially across different parts of the study. In contrast, amendments are changes to projects that have already been wholly approved.