

### Guidance on Amendments

In line with the statement on your favourable ethical opinion letter, you will need to notify us of any amendments to your study.

#### Minor amendments

If your amendment is considered to have no ethical implications, then it will be deemed to be minor and will not need to be reviewed by the University Ethics Committee (UEC). However, it will require evaluation by the Research Integrity and Governance Office (RIGO) and all amended documentation must be sent to your faculty ethics inbox:

[fhmsethics@surrey.ac.uk](mailto:fhmsethics@surrey.ac.uk)

[fassethics@surrey.ac.uk](mailto:fassethics@surrey.ac.uk)

[fepsethics@surrey.ac.uk](mailto:fepsethics@surrey.ac.uk)

Your submission should include a signed and completed Notification of Amendment Form, and any amended documentation related to the proposed Amendment. Please note all project documentation submitted for an amendment should have the version number incremented and **any new changed information/text highlighted in yellow highlighter**. In addition, **the strikethrough function should be used for any text that is no longer relevant**. If the documents do not reflect this, an application will not be considered valid and will be returned to the researcher.

This is also required in order that the UEC can demonstrate clear and transparent processes to external inspectors and regulators.

This is to ensure that reviewers can easily understand and identify the proposed changes and expedite an efficient turn around.

Please remember to quote your UEC reference in any queries regarding amendments; this will enable us to locate your original submission and assist a speedy passage through the Amendment process.

Examples of changes that fall within this category include:

- *Minor changes to the study documentation, e.g. correcting errors, updating contact details*
- *Changes to the research team (other than the lead researcher) including change of supervisor*
- *An extension to the study of up to 3 months beyond the period specified in the application form*
- *A change (whether this is an increase or decrease) of up to 10% in participant numbers compared to the original application*
- *Study suspension of up to 3 months from the date of the favourable ethical opinion (FEO)*

#### Substantial amendments

If your amendment has potential ethical implications, then it will be deemed to be substantial amendment and a review from the UEC is required. You will need to submit a completed Notification of Amendment form <add link> with all amended documentation to your faculty ethics inbox:

[fhmsethics@surrey.ac.uk](mailto:fhmsethics@surrey.ac.uk)

[fassethics@surrey.ac.uk](mailto:fassethics@surrey.ac.uk)

[fepsethics@surrey.ac.uk](mailto:fepsethics@surrey.ac.uk)

Your submission should include a signed and completed Notification of Amendment Form, and any amended documentation related to the proposed Amendment. Please note all project

documentation submitted for an amendment should have the version number incremented and any changes highlighted in yellow highlighter. This is to ensure that reviewers can easily understand and identify changes are proposed and will expedite an efficient turn around.

This is also required in order that the UEC can demonstrate clear and transparent processes to external inspectors and regulators.

Examples of changes that fall within this category include:

- *Changes to the design or methodology of the study, or background information affecting its scientific value*
- *Changes to procedures undertaken by participants*
- *Changes to inclusion and exclusion criteria*
- *Significant changes to study documentation, such as Participant Information Sheets, Consent Forms, questionnaires, invitation letters*
- *Appointment of a new lead researcher*
- *An extension to the study of over 3 months beyond the period specified in the application form*
- *A change (whether this is an increase or decrease) of over 10% in participant numbers compared to the original application*
- *Study halt to protect participants from harm*
- *Study suspension of over 3 months from the date of the FEO*
- *If the study has not started within a year of the date of the FEO*

Please note that in light of the Covid pandemic, the Notification of Amendment Form has been updated to safeguard both participants and researchers. If you had paused your project that previously had a FEO due to the pandemic, then you will need to follow the University process for restarting projects requiring face-to-face human contact. Details are available here: <https://www.surrey.ac.uk/coronavirus/researchers/research-university-ethics-committee-approval>

Please also note that we may not be able to review Amendment application from any project that has not been included in the First, Second or Third wave of Priority Lists immediately on receipt. Faculty-based Priority Lists have been drawn up by individual Faculties and the UEC has no influence on which projects are/are not included on these lists. You are referred to your local Associate Dean for Research for details of Faculty-based Priority Lists.

If your Amendment application is not part of the priority lists described above the UEC will try and process your application as soon as it possibly can and will make sure we stay in communication with you regarding the status of your application.

If you are in doubt or have any questions please contact RIGO at [ethics@surrey.ac.uk](mailto:ethics@surrey.ac.uk) or call 01483 68 9103 or 01483 682051.