

Amendments and Resubmission Policy

1. Minor Amendments

- **Examples:** Minor changes to the wording of consent forms, updates to contact information, or small adjustments to the study procedures that do not affect the risk to participants.
- **Review Process:** These amendments typically do not require a full ethics review and can be reviewed through an expedited process by the Chair or a designated member of the REC.
- **Additional fee: £75.00**

2. Significant Amendments

- **Examples:** Changes that affect the study design, methodology, participant population, or any aspect that could alter the risk to participants. This includes adding new study sites, significant changes to the intervention, or major revisions to the informed consent process.
- **Review Process:** Significant amendments usually require a full ethics review by the REC to ensure that the changes comply with ethical standards and do not increase the risk to participants.

3. Protocol for Amendments

- **Submission:** Researchers must submit an amendment application detailing the proposed changes and the rationale behind them.
- **Documentation:** All relevant documents, such as revised protocols, consent forms, and recruitment materials, must be included with the amendment application.
- **Review:** The REC will review the amendment application to determine whether a full review is necessary. If the changes are deemed significant, the full board will review the amendments at the next scheduled meeting.

4. Additional Fees

- **Significant Amendments:** If significant amendments are required, an additional resubmission fee will be applicable as the review committee will need to evaluate the ethics form again. The fee will be the same as the original fee advertised on the website.

In summary, minor amendments can often be reviewed through an expedited process, while significant amendments typically require a full ethics review to ensure continued compliance with ethical standards.