**UCL RESEARCH ETHICS COMMITTEE**

# Amendment Request Form

Please complete this form to make any amendments to an already approved study. Carefully read the information below to check that your planned changes are covered by this form. Once completed, submit your application to ethics@ucl.ac.uk for consideration by the UCL REC.

**Changes Covered by an Amendment Request:**

Amendments can cover a range of small changes as long as these are in line with and do not significantly deviate from the original approval. For example:

* Adding a new participant group or adding to participant numbers
* Asking for additional data from existing participants
* Adding or removing a group of participants or a research method from the project
* Applying for an extension to your current ethical approval – Studies can run for 5 years, after which a new ethics application must be submitted.

**Changes NOT Covered by an Amendment Request:**

Significant changes to your study are not covered by Amendment Requests and should be submitted as a new Ethics Application. Changes not covered by an amendment are, for example: substantial changes to the study aims or methodology, addition of an overseas location or any changes where the risks and ethical issues are vastly increased.

**Extensions:**

An extension after the end date for your study’s ethical approval is not possible and you will need to submit a new Ethics Application. Further, you will need to confirm that no data collection has taken place since the end date as collecting data without valid ethical approval could amount to research misconduct and may lead to disciplinary action. The total duration of a project, including any extensions, cannot normally exceed six years.

**Your Application Must Include:**

* A clear explanation of what the amendment you wish to make is and the justification for making the change.
* Details of all the ethical issues raised by the proposed amendments. This section must not be left blank.
* An updated version of your latest Ethics Application form, that includes all previous amendments, with your proposed amendments highlighted. This allows the reviewer to clearly see the changes and their effects and ensures the REC has an up-to-date overview of the study.
* All other updated documents, such as Participant Information Sheets, Consent Forms and recruitment adverts, similarly highlighted to reflect all changes.

If any of the above points are missing, your application will not be reviewed and will sent back to you.

**Review Process:**

Amendment Requests are reviewed by the original ethics reviewer, when possible. The time taken to review is dependent on the level of detail provided, the quality of the application and the availability of reviewers. As such, more complicated amendments are likely to take longer than simple, small changes.

**Amendment Request Form**

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| **1**  | **Ethics ID Number:**  |
| **2** | **Project Title:**  |
| **3** | **Name of PI:**  |
| **4** | **Name of Researcher(s) \*for student projects:**  |
| **5** | **Faculty and Department:**  |
| **6** | **Type of Research:**

|  |  |
| --- | --- |
| Undergraduate |[ ]  Staff |[ ]
| Postgraduate Research |[ ]  Postgraduate Taught |[ ]

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| **7** | **Date of Original Ethics Approval:**  |
| **8** | **Amendment start date:** *(List any requests for an accelerated review, due to funding reasons for example, and when the proposed changes are likely to be implemented).*  |
| **9** | **Has this study been amended before:**Yes[ ]       No [ ]  **If yes, how many amendment requests have been submitted prior to this one?** *(Please briefly describe all previous amendments and when they were approved).* |
| **10** | **Type of Amendment:***(Tick all that apply)*  Extension to approval (for 1 year) [ ] Data management/storage, retention and destruction  [ ] Research method/protocol  [ ] Location of research / research site / data source [ ] Participant group [ ] Sponsorship/Collaborators [ ] Information Sheet(s)/Consent Form(s) [ ] Consent method [ ] Data collection method [ ] Publication and sharing [ ] Recruitment Documents  [ ] Principal Investigator\*  [ ] Update to research instruments/tools [ ] Other (Please specify in section 11)  [ ]  \* To Note: *Additions to the research team, other than the Principal Investigator, the Student Supervisor and the Medical Supervisor, do not need to be submitted as an Amendment. An updated list can be emailed to**ethics@ucl.ac.uk**to keep on record.*   |
| **11** | **Details of Amendment(s):***(Describe the amendment(s) to be made to the project, in accessible language. Include any changes to be made to the data management aspects of the study. Also, indicate which sections these amendments change in your updated Ethics Application form which must be included as part of your application).*  |
| **12** | **Justification:***(Provide a brief explanation of why these changes are required and why they are needed now).* |
| **13** | **Ethical Considerations:***(Explain all new ethical issues raised by the amendment and how these will be addressed. This section must NOT be left blank).* |
| **14** | **Attachments:***(List which attachments have been included. To Note: ALL Amendment Requests must be accompanied by an updated and highlighted version of your latest Ethics Application and supporting documentation that include all previously approved amendments, as appropriate, except for solely extension requests).*   |
| **15** | **Declaration:** * I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
* I confirm that this amendment does not fundamentally change the study.
* I confirm that all relevant data protection arrangements are still in place for the duration of this amendment.
* I consider that it would be reasonable for the proposed amendments to be implemented.

**Principal Investigator Name\*:** **Principal Investigator Signature:****Date:** *\* To Note: The named Principal Investigator must sign this form. Applications submitted without this section having been completed by the PI will be returned to the applicant.* |

*Last updated February 2021*