### Application to amend an approved research ethics application

To be completed by the Principal Investigator in plain English and submitted to the Faculty Research Ethics Committee (FREC) that reviewed the original research ethics application.

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| **Principal Investigator’s details:** |  |
| **Name:** |  |
| **Address:** |  |
| **Telephone:** |  |
| **Email:** |  |

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| Full title of study: |  |
| Ethics application reference number: |  |
| Date study commenced: |  |
| Amendment number and date: |  |

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| **Type of amendment (indicate all that apply in bold)**(a) Amendment to information previously given on the University ethical review application form Yes No If yes, please refer to relevant sections of the FREC application in the “summary of changes” section below.(b) Amendment to the information sheet(s) and/or consent form(s) for participants, or to any other supporting documentation for the studyYes No If yes, please submit all revised documents with new version numbers and dates, highlighting new text using a different coloured font or the track changes feature. |

**Is this a modified version of an amendment previously notified to the FREC/ School REC and given an unfavourable opinion?**

 Yes No

**Is this an amendment to a project which underwent NHS ethical review?**

 Yes No

**Is sponsor sign off required for the amendment?**

 Yes No

**If applicable, has the amendment been submitted for NHS management permission (**[**R&D approval**](http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments)**)?**

 Yes No N/A

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| Summary of changesBriefly summarise the main changes proposed in this amendment using plain English. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained. |

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| Any other relevant informationApplicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the FREC is sought. |

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| High risk ethical issues

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|  | **Yes** | **No** |
| Does the study involve participants who are particularly vulnerable or unable to give informed consent (eg children, people with learning disabilities, your own students)? |  |  |
| Will the study require the cooperation of a gatekeeper for initial access to groups or individuals who are taking part in the study (eg students at school, members of self-help groups, residents of a nursing home)? |  |  |
| Will participants be taking part in the research without their knowledge and consent (eg covert observation of people in non-public places)? |  |  |
| Will the study involve discussion of sensitive topics (eg sexual activity, drug use)? |  |  |
| Are drugs, placebos or other substances (eg food substances, vitamins) going to be administered to the participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? |  |  |
| Will blood or tissue samples be obtained from the participants? |  |  |
| Is pain or more than mild discomfort likely to result from the study? |  |  |
| Could the study induce psychological stress or anxiety or cause harm or have negative consequences beyond the risks encountered in normal life? |  |  |
| Will the study involve prolonged or repetitive testing? |  |  |
| Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants? |  |  |
| Will the study involve an international collaborator or research conducted overseas?  |  |  |
| Will the study involve the transfer of data outside the European Economic Area? |  |  |
| Are there any potential conflicts of interest? |  |  |
| Does the research involve any risks to the researchers themselves, or individuals not directly involved in the research? |  |  |
| Will the study require ethical review from the NHS? (Refer to <http://ris.leeds.ac.uk/NHSethicalreview> for guidance in identifying circumstances which require NHS review) |  |  |

**If you answer yes to any of these questions please apply for full ethical review rather than an amendment:** [**https://secretariat.leeds.ac.uk/research-ethics/**](https://secretariat.leeds.ac.uk/research-ethics/)**.**  |

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| **List of enclosed documents** |
| *Document* | *Version* | *Date* |
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| 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 consider that it would be reasonable for the proposed amendment to be implemented.

*Signature of Principal Investigator:* …….………………………………*Print name:* …….………………………………*Date of submission:* …………………………………….*Signature of supervisor of student project:* …….………………………………*Print name:* …….………………………………*Date of submission:* ……………………………………. |

Please submit your form **by email** to the Faculty Research Ethics Committee which approved your original application:

Engineering and Physical Sciences: EPSResearchEthics@leeds.ac.uk

Biological Sciences: FBSResearchethics@leeds.ac.uk

Arts, Humanities and Cultures: AHCResearchethics@leeds.ac.uk

LUBS, Environment and Social Sciences: EthicsEnquiries@leeds.ac.uk

Medicine and Health: FMHUniEthics@leeds.ac.uk