# NOTICE OF AMENDMENT

For use in the case of all research previously approved by Imperial College Research Ethics Committee (ICREC) and Science, Engineering and Technology Research Ethics Committee (SETREC).

Please complete in language comprehensible to a lay person and submit to the Ethics and Research Governance Coordinator

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| Details of Principal Investigator (PI) |
| Name |  |
| Email*(Work not personal)* |  |

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| --- | --- |
| Full title of study |  |
| ICREC/SETREC reference number |  |
| Date study commenced |  |
| Amendment number |  |

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| Reason for Submitting Amendment |
|  | **Add Yes/No** |  |
| Change in Study Design or Documents  |  | *Please complete section 1 on page 2* *and declaration on page 4* |
| Request for Time Extension  |  | *Please complete section 2 on page 2 and declaration on page 4* |
| Change in Study Team |  | *Please complete section 3 on page 3 and declaration on page 4* |

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| Section 1 – Change in Study Design or Study Documents |
| Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. Please attach the amended study documents to this amendment application, giving the document name, version number and date in the table below. |
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| *Document Name* | *Version* | *Date* |
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| Section 2 - Request for Time ExtensionWhen was the original ICREC approval granted? Click or tap to enter a date.When would the PI require the ethical approval to be extended to? Click or tap to enter a date. *(no greater than 5 years from amendment submission)*Please give justification for the time extension request. |
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| Section 3 – Change in Study Team |
| *Please select from the following options:* | **Add** **Yes/No** |
| A study team member is leaving (excluding PI) |[ ]  *Please complete part A* |
| There is a new study team member (excluding PI) |[ ]  *Please complete part B* |
| There is a new CI  |[ ]  *Please complete part C* |
| Part A – A study team member is leaving |
| Name: |  |
| Title: |  |
| Position: |  |
| Location: |  |
| Email:*(Work not personal)* |  |
| Are they being replaced?  |  |
| Part B – There is a new study team member |
| Name: |  |
| Title: |  |
| Position: |  |
| Location: |  |
| Email:*(Work not personal)* |  |
| Summary of skills and experience **relevant to the area of this study:** |
| Part C – There is a New PI |
| Name |  |
| Title: |  |
| Position: |  |
| Location: |  |
| Email:*(Work not personal)* |  |
| Summary of skills and experience **relevant to the area of this study:** |
| The New PI must also read the following statement and sign their agreement:I declare that:* I undertake to abide by the ethical principles underlying the Declaration of Helsinki (1964) and subsequent amendments and good practice guidelines on the proper conduct of research.
* I undertake to abide by the Data Protection Act 2018 and General Data Protection Regulation (Europe) and any applicable local laws.
* I undertake to abide by all local laws and regulations for non-UK research.
* I will report any adverse or unforeseen events which occur to the Ethics and Research Governance Co-ordinator within 24 hours.
* I will provide an [annual progress report](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/6.-Annual-Progress-Report.docx) of the project until the end of the study.
* I will provide [notification of the end or early termination](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/7.-End-of-Study-Notification.docx) of the research project.
* I will provide [notification of amendment](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/imperial-college-research-ethics-committee/public/5.-Notice-of-Amendment.docx) to ICREC/SETREC if there are any changes to the research protocol or personnel which affect the ethical aspects of the project.
* I will assist ICREC/SETREC in any continuing review of the project deemed necessary by the Committee or Faculty Members.
* All information on this form is correct.
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| Signed:  |  |
| Date:  |  |

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| Section 4: Any other relevant information |
| Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of ICREC/SETREC is sought. |
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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.
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| Signature of Principal Investigator: |  |
| Print name: |  |
| Date of submission: |  |