**St. George’s School of Health and Medical Sciences**

 **Research Ethics Committee**

**Joint Research and Enterprise Services**

**Ground Floor, Jenner Wing**

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| Notice of Study Amendment |

\*\*\*\*\*\*DELETE EVERYTHING BETWEEN THE ASTERISKS BEFORE SUBMITTING\*\*\*\*\*\*

**Instructions for Completion**

This guidance is designed to help you complete the Notice of Study Amendment for submission to St. George’s Research Ethics Committee (SGREC).

We have colour coded the template to provide you with the following:

1. Text in red is for instructions only and needs to be deleted when the information required for that particular section is completed. Therefore please ensure any entry you make on to this form is in black.
2. **Text in black (bold)** should not be deleted as it is integral to the application form and ensures you have included all relevant information about your project. **Any existing black text should not be amended or deleted.**
3. **Text in grey** indicates an interactive field.

Please ensure that you add the study title, version and date to the document footer.

If you have any questions about completing the APR, please contact the Research Ethics Officer at sgulrec@sgul.ac.uk.

DELETE ALL RED TEXT BEFORE SUBMITTING

IF YOU DO NOT DO SO YOUR APPLICATION WILL BE RETURNED TO YOU AND YOU WILL BE ASKED TO AMEND IT ACCORDINGLY

PLEASE DELETE THE “INSTRUCTIONS FOR COMPLETION” SECTION BEFORE SUBMITTING YOUR FORM

\*\*\*\*\*\*\*DELETE EVERYTHING BETWEEN THE ASTERISKS BEFORE SUBMITTING\*\*\*\*\*\*

|  |  |
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| **Full study title:** |  |
| **Reference number:** | xxxx.xxxx |
| **Type:** | Please select |  |
| **Study Design:** | Please select |  |
| **Study Duration** | **Planned start date:** | **Planned end date:** |
| Click here to enter a date |  Click here to enter a date |
| **Actual start date:** |  |
| Click here to enter a date. |  |
| **Notice of study amendment version number:** |  | **Date of this notice:** | Click here to enter a date |

This form is for use in the case of all research previously approved by St George’s Research Ethics Committee (SGREC).

Please complete in language comprehensible to a lay person and submit to the SGREC Ethics and Integrity Officer at sgulREC@sgul.ac.uk.

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| Section 1: Personnel details |

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| **Chief Investigator/academic supervisor (delete as appropriate)** |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |

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| **Student (delete if not applicable)** |
| **Name** |  |
| **Course title** |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |

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| **Clinical supervisor (delete if not applicable)** |
| **Name** |  |
| **Position** |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |

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| **Other investigators/collaborators (delete if not applicable; add additional rows if necessary)** |
| **Name** |  |
| **Position** |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |

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| **Statistician (delete if not applicable)** |
| **Name** |  |
| **Position** |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |

**Reason for Submitting Amendment**

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| --- | --- |
| **Change in study design or documents (including minor document changes)** |[ ]  Please complete **Section 2** and **Section 6.** |
| **Request for time extension** |[ ]  Please complete **Section 3** and **Section 6** |
| **Change in study team** |[ ]  Please complete **Section 4** and **Section 6** |

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| Section 2: Change in study design or study documents |

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| 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. |
|  |
| **Document name** | **Version number** | **Date** |
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| Section 3: Request for time extension  |

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| **Date of favourable ethical opinion from SGREC:** | Click here to enter a date. |
| **Date to which request for extension is made:** | Click here to enter a date. |
| **Please give justification for the time extension request.** |
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| Section 4: Change in study team  |

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| A study team member is leaving (excluding CI) |[ ]  Please complete **Section 4a** |
| There is a new study team member (excluding CI) |[ ]  Please complete **Section 4b** |
| There is a new CI |[ ]  Please complete **Section 4c** |

**4a) A study team member is leaving (excluding CI)**

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| **Details of team member leaving** |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Is this person being replaced?** | Yes [ ] No[ ]  |
| **New team member’s details** |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

**4b) There is a/are new team member(s) (excluding CI)**

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| **New team member’s details (please add additional tables if there is more than one new team member)** |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

**4c) There is a new CI**

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| **Chief Investigator** |
| **Name** |  |
| **Position** |  |
| **Affiliation** | Choose an item. |  |
| **Address (inc. postcode)** |  |
| **Phone number** |  |
| **Email address** |  |
| **Summary of experience relevant to this project** |  |

The new CI must also read the following statement and sign to demonstrate their agreement:

The Chief Investigator certifies that all information provided in this document is accurate.

The Chief Investigator has read and understood the approved protocol and associated study documents and will conduct the study according to these documents. No deviation from the protocol will be implemented without the prior review and approval of St. George’s Research Ethics Committee (SGREC) except where it may be necessary to eliminate an immediate hazard to a research participant. In such case, the deviation will be reported to the SGREC within 7 days. The SGREC will be informed if there are any changes made to the research protocol, personnel or other study documents via an amendment submitted to the SGREC.

The study will be conducted in compliance with the approved protocol, the UK Data Protection Act (2018), the UK Policy Framework for Health and Social Care Research 2017, and any other applicable regulatory requirement(s), as appropriate. The study shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the UK country in which the study site is located, including but not limited to The Human Rights Act 2018, the Data Protection Act 2018 and the World Medical Association Declaration of Helsinki entitled “Ethical Principles for Medical Research Involving Human Subjects” (2013 version). If the research site(s) is/are located outside of the UK, the study will be conducted in compliance with all local ethical, regulatory and legal requirements for the research to be conducted in that country or countries.

Furthermore, alongside the study team, the Chief Investigator agrees to provide an annual progress report of the study until the end of the study and notify the SGREC of the end or early termination of the research project. The Chief Investigator and study team will assist the SGREC in any continuing review of the project deemed necessary by the SGREC, and the will otherwise reapply for ethical approval after 5 years.

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| Chief Investigator (delete as appropriate) | Insert NameInsert PositionEmployer (e.g. SGUL/SGHT etc) (delete as appropriate) | (CI– delete before printing and signing. Electronic signatures are accepted) |
|  |  | Date: | Click here to enter a date. |

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| Section 5: Any other relevant information  |

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| Applicants may indicate below any specific ethical issues relating to the amendment, on which the opinion of SGREC is sought. |
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| Section 6: 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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| Chief Investigator (delete as appropriate) | Insert NameInsert PositionEmployer (e.g. SGUL/SGHT etc) (delete as appropriate) | (CI– delete before printing and signing. Electronic signatures are accepted) |
| Date: | Click here to enter a date. |