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| Amendment Request Form | | | | | |
| For an amendment to an ethically approved research project, submit the completed form to the reviewing Human Research Ethics Committee (HREC).  **An amendment must not be implemented at a site until HREC approval has been given and (if applicable) Site Specific Assessment (SSA) amendment has been authorised.** | | | | | |
| Research Project | | | | | |
| HREC reference number | e.g. HREC/17/Abc/123 |  | | HREC approval date | Select date |
|  | | | | | |
| Local reference number | Enter text |  | | Date of this form | Select date |
|  | | | | | |
| Project title | Enter text | | | | |
|  | | | | | |
| Sponsor | Enter text |  | | Sponsor telephone | Enter text |
|  | | | | | |
| Sponsor contact (Aus) | Enter text |  | | Sponsor email | Enter text |
|  | | | | | |
| Sponsor billing address | Enter text | | | | |
|  | | | | | |
| Coordinating Principal Investigator (CPI) for project | | Enter text | | | |
|  | | | | | |
| CPI email | Enter text |  | |  |  |
|  | | | | | |
| Study coordinator name | Enter text |  | | Study coordinator email | Enter text |
| Amendment | | | | | |
| Did a commercial sponsor initiate the amendment? | | | | | Select one |
|  | | | | | |
| Amendment category | | | Select one | | |
|  | | | | | |
| Amendment category 2 *(if applicable)* | | | Select one | | |
|  | | | | | |
| Amendment category 3 *(if applicable)* | | | Select one | | |
|  | | | | | |
| Description of changes | Enter text | | | | |
|  | | | | | |
| Reason for changes | Enter text | | | | |
|  | | | | | |
| Do the changes raise any ethical issues? | | | | | Select one |
|  | | | | | |
| Do the changes raise any privacy (including data linkage) issues? | | | | | Select one |
|  | | | | | |
| If Yes, provide description of ethical and/or privacy issues | | Enter text | | | |
|  | | | | | |
| Does the amendment include additional/different drugs/devices or involve a new indication for any drug/device other than that approved in the original application? | | | | | Select one |
| Participating Sites | | | | | |
| Does the amendment affect all sites approved by the reviewing HREC? | | | | | Select one |
|  | | | | | |
| If No, list affected sites | Enter text | | | | |
| *An amendment to an ethically approved research project may also impact research governance/Site Specific Assessment (SSA). The Research Governance Officer (RGO)at each affected site must be notified of the amendment by the site PI, in order to determine if research governance/SSA amendment is required.* | | | | | |
| Supporting Departments | | | | | |
| Does the amendment impact the type or frequency of service provided by a supporting department at participating sites? | | | | | Select one |
|  | | | | | |
| If Yes, list department(s) | Enter text | | | | |
| *Supporting departments may include: Anaesthesia, Anatomical pathology, Cardiology or ECG, Chemical pathology, Clinical immunology, Clinical pharmacology, EEG or EMG, Emergency, Endocrinology, Haematology, Health information, Interpreter services, Medical staff, Molecular biology, Nuclear medicine, Nursing services, Occupational therapy, Ophthalmology, Pharmacy, Physiotherapy, Radiology, Social work, Speech pathology, Tissue typing.* | | | | | |
| Amended Documents | | | | | |
| Document title *(include version number, if applicable)* | | | | | **Version Date** |
| Enter text | | | | | Select date |
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| Declaration | | | | | |
| *To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.* | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended. | | | | | |
|  | | | | | |
| Name | Enter text |  | | Email | Enter text |
|  | | | | | |
| Organisation | Enter text |  | | Telephone | Enter number |

**Signature**

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**Date** Select date

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| *Office use only* | | | | |
| Research office acknowledgement – HREC | | | | |
| Name | Enter text |  | Position | Enter text |
|  | | | | |
| Comment | Enter text | | | |

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**Signature**

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**Date** Select date

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| Research office acknowledgement – RGO | | | | | | |
| Name | | Enter text |  | Position | | Enter text |
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| Comment | | Enter text | | | | |

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**Signature**

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**Date** Select date

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