Amendment Application Form

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| **STUDY DETAILS** | |
| **AHCL HREC Project ID:** |  |
| **Project Title:** |  |
| **Protocol No. (if applicable):** |  |
| **Principal Investigator:** |  |
| **Date of this Application:** |  |

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| **DETAILS OF AHCL ETHICS APPLICATION** | | | |
| **Ethics review only** | | **Ethics and Governance** | |
| **Date of Ethical Approval:** |  | **Date of Ethical Approval Expiry:** |  |

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| **AMENDMENT CATEGORY**  You may select more than one | |
| **Protocol** |
| **Investigator Brochure** |
| **Participant Information and Consent Form (PICF)** |
| **Other supporting document:** |
| **Ethics Extension** (please note: HREC will only extend a study for one additional year beyond 5 years) |
| **Change of investigator, coordinator or sponsor** |
| **Other:** |

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| **AMENDED DOCUMENTS**  Each document listed much be attached to this submission | |
| **File name:**  **Version and date:** |
| **File name:**  **Version and date:** |
| **File name:**  **Version and date:** |
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| **File name:**  **Version and date:** |
| **Total number of amended documents attached to this submission:** |

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| **AMENDMENT REASON AND DETAILS** | | | |
| **Change of study design** (for example, addition of an arm, change to an intervention) | | | |
| **Please explain why and how an amendment to the study design is required:** | | |  |
| **Extension of ethical approval** | | | |
| **Please explain why this is required:** | | |  |
| **Change of investigator** | | | |
| **Addition of investigator** | | Name: |  |
| Role: |  |
| CV attached (please note CV must have been updated, signed and dated within the past two years) | |
| GCP certificate attached | |
| **Deletion of investigator** | | Name: |  |
| Role: |  |
| **Change of coordinator** | | | |
| **Addition of coordinator** | | Name: |  |
|  | | Role: |  |
| **Deletion of coordinator** | | Name: |  |
|  | | Role: |  |
| **Change of sponsor** | | | |
| **New sponsor details:** | Name: | |  |
| ABN: | |  |
| Contact name: | |  |
| Address: | |  |
| Email: | |  |
| Phone: | |  |
| **Other** | | | |
| **Please describe:** |  | | |

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| **ETHICAL AND PRIVACY IMPLICATIONS** | |
| **Do the changes raise any privacy issues (including data linkage issues)?** | No  Yes (please detail below) |
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| **Has any potential impact to participants resulting from the amendment been addressed in the PICF?** In answering this question you must give consideration to clause 5.3.6*[[1]](#footnote-1)* in the *National Statement on Ethical Conduct in Human Research (NHMRC, 2023)*. | Yes: please attach a tracked change copy of the PICF  No, as amendment does not impact participant interests  Not applicable, as Waiver of Consent obtained |
| **If a Waiver of Consent was obtained, please indicate whether you can still fulfil the necessary conditions in light of this amendment.** In answering this question you must give consideration to clause 2.3.10[[2]](#footnote-2) in the *National Statement on Ethical Conduct in Human Research (NHMRC, 2023)*. |  |

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| **TGA CONSIDERATIONS**  Complete this section only if the study is being conducted at an AHCL facility | |
| **Does the amendment include different drugs/devices or involve a new indication for any drug/device?** | No  Yes: please detail below and attach the TGA  pathway (CTN or CTA confirmation) |
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| **SUPPORTING RESOURCES AT AHCL** | |
| **Are additional AHCL resources (other than those approved originally) required as a result of the amendment?**  These could be clinical/ nonclinical staff or new department (for example, IS, theatres). | No  Yes: please detail below |
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| **ADDITIONAL COMMENTS** |
| **Please add any further information you feel may be relevant:** |
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| **DECLARATION** | |
| I declare that 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, 2023)* and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016)*, or as amended. | |
| **Principal Investigator / Supervisor signature:** |  |
| **Date:** |  |

1. 5.3.6 in the *National Statement on Ethical Conduct in Human Research (NHMRC, 2023)*: Researchers should present information about the research to participants in ways that help them make informed choices about their participation and support them in those decisions and in their participation. Researchers should consider:

   (a) whether the information about the research is best communicated to participants through speech, writing, visually or in some other way, or a combination of these;

   (b) the need for accurate and reliable translation (written and/or oral) of the information into a participant’s first language or dialect;

   (c) the participant’s cultural background and its potential effects on the communication process;

   (d) the participant’s educational background and level of literacy, numeracy and understanding of scientific and academic concepts, if known;

   (e) the participant’s age and level of maturity; and

   (f) any visual, hearing or communication impairment with which the participant is living. [↑](#footnote-ref-1)
2. 2.3.10 in the *National Statement on Ethical Conduct in Human Research (NHMRC, 2023)*: Before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that:

   a) involvement in the research carries no more than low risk to participants (see Chapter 2.1).

   b) the benefits from the research justify any risks of harm associated with not seeking consent

   c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

   d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

   e) there is sufficient protection of their privacy

   f) there is an adequate plan to protect the confidentiality of data

   g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

   h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

   i) the waiver is not prohibited by State, federal, or international law. [↑](#footnote-ref-2)