Annual Progress / Final Report – AHCL Human Research Ethics Committee

This report is to be completed every twelve months following the date of HREC approval, and at the completion of your research project. The **signed** report can be submitted by email to research@sah.org.au.

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

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| **ETHICS APPROVAL**Please note: AHCL HREC has granted ethical approval for this study for five years, contingent on the submission of an Annual Progress Report. By completing an Annual Progress Report, you will be granted approval to continue your research until the date that ethical approval expires. |
| **Date of Ethical Approval:** |  |
| **Date of Ethical Approval Expiry:** |  |
| **Annual Report Due Date:** |  |
| **Is an extension being sought for this study?** If you wish to extend the five year ethical approval for a further 12 months you must complete and submit the *Amendment Application Form* to the Research Office no later than three months before ethical approval expires.  | [ ]  No [ ]  Yes (please attach completed *Amendment Application Form*) |

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| **STUDY STATUS** |
| **This is an Annual Progress Report if one or more of the following is checked:**[ ]  Not yet commenced[ ]  In Progress[ ]  Completed recruitment | **This is a Final Report if one of the following is checked:**[ ]  Completed[ ]  Withdrawn (not commenced)[ ]  Terminated (forced study closure), please provide details |
| **Details of termination:** |  |
| **Estimated completion date:** |       | **Date of completion or termination:** |       |

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| **AHCL HREC APPROVED SITES** |
| **Site** (site name and address) | **Status of Individual Sites** (e.g. Not yet commenced, Active, Closed) | **Principal Investigator** |
|       |       |       |
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| **DATA RECORDS**Applies to RETROSPECTIVE studies only. Each record encapsulates all the details reviewed for a single participant. |
| **Number of data records reviewed as part of this study:** |       |
| **Is this consistent with the number stated in the Protocol?**If No, please explain below. | [ ]  Yes[ ]  No |
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| **PARTICIPANT DATA**Applies to PROSPECTIVE studies only |
| **Planned recruitment:** |       | **Actual recruitment:** (since study commenced) |       |
| **Is recruitment on target?**If No, please explain why recruitment is behind schedule. Describe steps taken/to be taken to boost study recruitment. | [ ]  Yes[ ]  No |
|       |
| **Number of active Participants:** (at the time of reporting) |       |
| **Number of Participants completed the study:**(since study commenced) |       |
| **Number of Participants withdrawn:**(since study commenced) |       |
| **Is the rate of Participant withdrawal consistent with the anticipated rate?** | [ ]  Yes[ ]  No |
| **Is the rate of loss to follow-up consistent with the anticipated rate?** | [ ]  Yes[ ]  No |

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| **PROGRESS SUMMARY** |
| **Please provide a short statement regarding the progress of the project over this reporting period:**If there are publications or conference proceedings arising from this study, please attach them to this report. |       |
| **Have you attached relevant publications to this report?** | [ ]  Yes[ ]  N/A |
| **Current approved version of the protocol recognised by the AHCL HREC:** |       |
| **Is the AHCL HREC recognised version correct:** | [ ]  Yes[ ]  No |
| **If No, please list the current protocol details (version and date):**Please immediately complete an *Amendment Application Form* and submit it to the Research Office. |       |
| **Have there been any changes to your research project since ethics approval was granted?**For example: participating investigators, including Principal Investigator, protocol, patient information sheet/consent form, methodology, data collection instruments, investigator brochure, risk or benefit information. | [ ]  Yes[ ]  No |
| **Have these changes been submitted to the AHCL HREC as amendments?**If No, please immediately complete an *Amendment Application Form* and submit it to the Research Office. | [ ]  Yes[ ]  No [ ]  N/A |

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| **SAFETY REPORTING**Please complete this section only if the study is a **clinical trial**. |
| **Please submit Safety Report(s) for this year, as per the study protocol, e.g. from the Independent Data Safety Monitoring Board (DSMB) or other independent safety monitoring body.**Please attach a copy to this report. | Copy attached?[ ]  Yes[ ]  No |
| **Have all Significant Safety Issues (SSIs) been reported to the HREC?**If No, please explain below. | [ ]  Yes[ ]  No[ ]  N/A |
|       |
| **Have all Serious Breaches of Good Clinical Practice or Protocol been reported to the HREC?**If No, please explain below. | [ ]  Yes[ ]  No[ ]  N/A |
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| **COMPLIANCE WITH THE CONDITIONS OF ETHICAL APPROVAL AND THE NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS**Please comment on the following: |
| **Maintenance and security of study records** |
| **Where is this data stored? Who has access to it?** |       |
| **Have all individuals who have access been authorised by the respective site governance office?** |       |
| **Has all study data been stored in line with the ethically approved Protocol?** | [ ]  Yes[ ]  No |
| **Participant Consent** |
| **Have all Participants been consented in accordance with the ethically approved protocol?** | [ ]  Yes[ ]  No[ ]  N/A (Waiver of Consent applies) |
| **Study Conduct** |
| **Has the study been conducted in accordance with the ethically approved protocol?** |       |

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| **HAVE ANY OF THE FOLLOWING EVENTS OCCURRED?** |
| **Have there been any unforeseen events or new information that may affect the continued ethical approval of the project, which has not been previously reported to the AHCL HREC?**If Yes, please give details below, and attach relevant documents to this report. | [ ]  Yes[ ]  No |
|       |
| **Have there been any complaints received from Participants or other persons involved in the research?**If Yes, please give details of the event/s and how it was resolved or addressed and identify whether the event/s occurred within sites approved by AHCL HREC. | [ ]  Yes[ ]  No |
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| **DISCLOSURES AND CONFLICTS OF INTEREST** |
| **Researchers are required to understand their responsibilities regarding conflicts of interest.** The [*Australian Code for the Responsible Conduct of Research 2018*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018) is the foundation for responsible research conduct.The *Disclosure of interests and management of conflicts of interest* guide is also available on the [NHMRC website](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#download) (scroll down on that page). Please review this guide and disclose any conflict of interest that may have emerged since approval or the last progress report |
| **Are there any new conflicts of interest to declare?**If Yes, please detail below. | [ ]  Yes[ ]  No |
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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 I have given is true and that my research has contravened neither the *National Statement on Ethical Conduct in Human Research (2023)*; the *Health Records and Information Privacy Act 2002 (NSW)*, the *Privacy Act 1988 (Commonwealth)*, nor the Adventist HealthCare Limited HREC conditions of approval for the ethical conduct of research.I also declare that I have respected the mental and physical welfare, rights, dignity, beliefs, consent and safety of the individual participants in the conduct of my research.  |
| **Principal Investigator / Supervisor signature:** |  |
| **Date:** |       |
| **Student (if applicable) signature:** |  |
| **Date:** |       |