Participant Information and Consent Form

[Insert title of study]

**PARTICIPANT INFORMATION SHEET**

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| **STUDY DETAILS** |
| **AHCL HREC Project ID:** | [insert] |
| **Project Title:** | [insert] |
| **Project Sponsor:** | [Project Sponsor in Australia] |
| **Principal Investigator:** | [insert] |
| **Associate Investigator(s):** | [insert] |
| **Student Researcher:** | [delete if not applicable] |
| **Location:** | [Location where the research will be conducted] |

**Invitation**

You are invited to participate in a research study involving [insert] at the Sydney Adventist Hospital. This procedure involves [insert short description of procedure].

The study is being conducted by Dr [insert] and [insert].

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

**1. What is the purpose of this study?**

[Insert text]

**2. Why have I been invited to participate in this study?**

You are eligible to participate in this study because [Insert text]

**3. What if I don’t want to take part in this study, or if I want to withdraw later?**

[Insert text]

**4. What does this study involve?**

If you agree to participate in this study, [insert text]

**5. How is this study being paid for?**

[Insert text]

**6. Are there risks to me in taking part in this study?**

[Insert text]

**7. What happens if I suffer injury or complications as a result of the study?**

[Insert text]

**8. Will I benefit from the study?**

This study aims to further medical knowledge and may improve future implementation of new surgical procedures such as [insert]. However, it will not directly benefit you.[add or delete if necessary]

**9. Will taking part in this study cost me anything, and will I be paid?**

Participation in this study will not cost you anything, nor will you be reimbursed for participating in the study. [add or delete if necessary]

**10. How will my confidentiality be protected?**

Of the people treating you, only [insert doctor’s name] will know whether or not you are participating in this study. Any personal identifiable information, such as name, address, and phone number will not be included in the study [add or delete if necessary]. The research database will be compiled without the use of personal identifiers. The database will be held securely at [insert].

**11. What happens with the results?**

If you give us your permission by signing the consent document, we plan to discuss the results and potentially publish them in a local journal article. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish. [add or delete if necessary]

**12. What happens to my treatment when the study is finished?**

This study has no bearing at all on the direction of your treatment. This study is analysing the data that is collected as part of your routine care (called retrospective analysis). [amend/expand or delete if necessary] Data will be collected prospectively as part of your participation in this study. [amend/expand or delete if necessary]

**13. What should I do if I want to discuss this study further before I decide?**

When you have read this information, [insert] will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact [insert].

**14. Who should I contact if I wish to withdraw from the study?**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project, if you would like to withdraw your consent to take part in this study or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study researcher on [insert name and phone number]or any of the following people.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are as follows:

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| --- |
| **Research Office - Adventist Healthcare Limited**185 Fox Valley Rd, Wahroonga NSW 2076 |
| **Phone:** | 02 9480 9604 | **Email:** | research@sah.org.au |

Reviewing HREC approving this research:

|  |  |
| --- | --- |
| **Reviewing HREC Name:** | Adventist HealthCare Limited HREC |
| **Phone:** | 02 9480 9604 | **Email:** | research@sah.org.au |

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

**CONSENT FORM**

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| **STUDY DETAILS** |
| **AHCL HREC Project ID:** | [insert] |
| **Project Title:** | [insert] |
| **Project Sponsor:** | [Project Sponsor in Australia] |
| **Principal Investigator:** | [insert] |
| **Associate Investigator(s):** | [insert] |
| **Student Researcher:** | [delete if not applicable] |
| **Location:** | [Location where the research will be conducted] |

**Declaration by Participant**

* I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
* I understand the purposes, procedures and risks of the research described in the project.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received.
* I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
* I understand that I will be given a signed copy of this document to keep.

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| **Name of Participant** (please print) |  |
| **Participant Signature:** |  | **Date:** |  |
| **Witness Signature:** |  | **Date:** |  |

**Declaration by Consenting Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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| **Name of consenting Study Doctor/ Senior Researcher†** (please print) |  |
| **Signature:** |  | **Date:** |  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**FORM FOR WITHDRAWAL OF PARTICIPATION - *Adult providing own consent***

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

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| **Project Sponsor:** | [Project Sponsor in Australia] |
| **Principal Investigator:** | [insert] |
| **Associate Investigator(s):** | [insert] |
| **Student Researcher:** | [delete if not applicable] |
| **Location:** | [Location where the research will be conducted] |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

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| **Name of Participant** (please print) |  |
| **Signature:** |  | **Date:** |  |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher† witnessing study withdrawal**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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| **Name of Study Doctor/ Senior Researcher† witnessing study withdrawal** (please print) |  |
| **Signature:** |  | **Date:** |  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.