[Insert institutional letterhead]

[insert name of local institution/s where research is being conducted]

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

**[STUDY TITLE]**

[Use plain English equivalent if a technical title]

**Invitation**

You are invited to participate in a research study into [*lay* *description of study*].

The study is being conducted by... [*names, positions, departments – if several, list them one under the other for clarity*].

*[If appropriate]*: The study is part of a national/international collaborative study coordinated by [*Australian, European, US researchers*].

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?**

The purpose is to investigate whether [*insert*].

*[Where the study is for the purpose of obtaining a degree or other student project please mention this here]*

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

You are eligible to participate in this study because [*insert].*

1. **What are my healthcare rights?**

The Australian Charter of Healthcare rights applies to all individuals within the healthcare system and provide the right to accessible services, safety, respect, partnership, privacy and the right to provide feedback to healthcare providers. You have the right to consent that is based on an informed decision and without influence.

For more information on the Australian Charter of Healthcare Rights, please scan the QR code provided, or visit <https://www.safetyandquality.gov.au/consumers/working-your-healthcare-provider/australian-charter-healthcare-rights>

If you are of Aboriginal or Torres Strait Islander origin, please indicate on the consent form below whether you would like your details to be provided to the [insert study site name] Aboriginal Hospital Liaison Officer. If you choose for your details to be passed on, the Liaison Officer will contact you to offer further support opportunities if required.

1. **What does participation in this study involve?**

If you agree to participate in this study you will then be asked to [*list everything participants will be required to do as part of their participation e.g. nature, number, timing and time commitment of procedures, visits, questionnaires, interviews etc - giving an outline of the nature of the questions where appropriate]*

[*If planning to access participant’s health information please add the following*]. By signing the consent form attached you are also giving us permission to access your medical records to collect the relevant study data such as [*give details of type of data items to be collected e.g. demographic details, diagnosis and treatment etc*] Any information obtained in connection with this research project that can identify you will remain confidential.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

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

Participation in this study is voluntary. It is completely up to you whether or not you participate. [*If appropriate*] If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

[*If appropriate*: *insert any potential consequences that might arise from withdrawing from the study, for example…*] However, it may not be possible to withdraw your study samples or your data from the study results if these have already had your identifying details removed.

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

The study is being paid for by [*name of commercial entity, granting body, departmental funds etc*].

[*If appropriate*] Any money received to run the project will be deposited into an account managed by [*insert hospital/Area Health Service*].

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

The only foreseeable risk/s in taking part in this study is/are [*Provide information on inconvenience, reasonable foreseeable risks or discomforts that may occur* e.*g. the inconvenience of an additional visit/short telephone call etc]*

*[Where psychological distress may be a consequence]* You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This will be provided free of charge.

*[For group discussions]* Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting

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

If you require treatment or suffer loss as a result of the negligence of any of the parties involved in the study you may be entitled to compensation; the cost of your treatment would have to be paid out of such compensation.

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

This study aims to further medical knowledge and may improve future treatment of [*name of disease or condition, as appropriate*], however it [*may not / will not]* directly benefit you.

1. **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 paid. [*If applicable]* You will be reimbursed for your time and reasonable travel expenses to the amount of ……. [I*f applicable*] Meals will be provided during the study visits.

1. ***[If appropriate]* What will happen to my tissue sample after it has been used?**

The blood or tissue sample/s you provide during the study will be [*stored/destroyed*] at the completion of the study. If the researchers wish to store (or ‘bank’) the samples, you will be asked whether you agree to this and, if so, will be asked to sign a specific consent form.

If you do agree to your tissue samples being stored, they will not be used for other research projects, except with your written consent or, under some circumstances, with the approval of a Human Research Ethics Committee at that time.

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

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above [*insert details of others - as appropriate*] will have access to your details and results that will be held securely at [*institution*].

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

If you give us your permission by signing the consent document, we plan to discuss/publish the results [*state the persons/agencies to whom the information will be disclosed, the nature of the information disclosed and the purpose of the disclosure e.g. the sponsor for monitoring purposes, the HREC for monitoring purposes, peer-reviewed journals, presentation at conferences or other professional forums*].

In any publication, information will be provided in such a way that you cannot be identified.

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

When you have read this information, the researcher [*name*] 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 him/her on [*number – or other if different*].

1. **Who should I contact if I have concerns about the conduct of this study?**

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on (02) 8797 7605, or email SESLHD-RSO@health.nsw.gov.au and quote [*HREC project number*].

[*Multi-site research only* ] The conduct of this study at the [*name of site*] has been authorised by the [*name of health district*]. Any person with concerns or complaints about the conduct of this study may also contact the [*details of the Research Governance Officer of the health district*]

**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.**

***[Insert institutional letterhead]***

***[name of local institution/s where research is being conducted]***

## CONSENT FORM

[To be used in conjunction with a Participant Information Sheet]

**[STUDY TITLE]**

[Use plain English equivalent if a technical title]

1. Are you of Aboriginal or Torres Strait Islander origin?

 ☐ No

☐ Yes, Aboriginal

☐ Yes, Torres Strait Islander

☐ Yes, both Aboriginal and Torres Strait Islander

2. I,................................................................................................................. of................................................................................................................

agree to participate in the study described in the participant information statement set out above ***(or: attached to this form).***

3. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

4. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

5. I understand that I can withdraw from the study at any time without prejudice to my relationship to the **([insert or delete as necessary]** ***University [name] and the*** *......****Hospital, Research Institute).***

6. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

7. I understand that if I have any questions relating to my participation in this research, I may contact Dr ............................on telephone................., who will be happy to answer them.

8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, email SESLHD-RSO@health.nsw.gov.au .

# Signature of participant Please PRINT name Date

# [*or person responsible] (insert or delete as necessary*)

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**Signature of witness Please PRINT name Date**

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# Signature of investigator Please PRINT name Date

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**[Institutional letterhead]**

**[Insert name of local institution where research is being conducted]**

**[STUDY TITLE]**

[Use plain English equivalent if a technical title]

## REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the (*University...[insert name of university], Hospital or my medical attendants)*.

# Signature of participant Please PRINT name Date

# [*or person responsible] (insert or delete as necessary*)

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The section for Revocation of Consent should be forwarded to **(INSERT name and address of Principal Investigator).**