**[Insert institutional letterhead]**

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

PARTICIPANT / SUBSTITUTE CONSENT *[delete where not applicable]* INFORMATION SHEET AND CONSENT FORM

*[for substitute consent make relevant throughout document]*

TRIALS INVOLVING GENETIC TESTING

AND COLLECTION OF HUMAN TISSUE

**[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 [*Australia, 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 the study?**

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

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

You have been invited 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 this on the provided consent form below and your details will be provided to the [insert study site name] Aboriginal Hospital Liaison Officer. The Liaison Officer will contact you to offer further support opportunities if required.

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

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

The study procedure involves

removal of a new sample of [*X amount of* *blood, tissue - specify*]. OR

removal of [*X amount of* *blood, tissue - specify*] taken during the clinical procedure where [*specify*]. OR

accessing your previously stored sample.

These samples will be *examined/tested* by [*describe the process*] to determine [*insert purpose of test*].

[*If appropriate*] In addition, the researchers would like to have access to your medical record to obtain information relevant to the study. This information will include the following [*list data items to be collected*]

1. **What are the risks associated with this procedure?**

[*As appropriate*]: You may experience some mild discomfort and minor bruising or swelling at the site where blood sampling is collected. OR

There are no additional risks involved in participating in this study. The tissue sample used for the study is taken from the tissue that is being removed during your [*state procedure]*. No additional tissue will be taken. OR

There are no additional risks involved in participating in this study. Your sample was collected on a previous occasion.

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

*[If appropriate]*: The testing will not provide you with any direct benefit because the link between you and your sample will be removed before your sample is analysed. However, it may provide valuable information to improve the management of people with [*specify condition/disease*] in the future. OR

You will be contacted if the testing shows important information for you, and you will be asked if you wish to know the results. The results may be important to you where they provide information about:

* A risk of an inherited condition AND/OR
* Information that may reveal non-paternity, non-maternity, or non-relationship to siblings; AND/OR
* Information that might influence a decision to have children AND/OR
* Information that might affect your ability to obtain insurance or employment.

Should you wish to know these results, expert counselling will be provided by [*state where*] to explain what the results mean for you and to support you as necessary.

*[If appropriate]*: It may also be necessary to refer you for re-testing by genetic services outside this study.

1. **What happens if I don’t want to take part in the study?**

Participation in this study is voluntary. It is completely up to you whether or not you participate. 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.

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

Your sample will not be linked to your name or any personal details. The link between this information and your sample will be removed before your sample is analysed. Your test results will not be linked to you.

OR

Although your sample will be linked to information identifying you, all aspects of this study will be kept confidential and only those conducting and monitoring the study will have access to your results.

We plan to discuss/publish the findings. (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.

*[If appropriate*]: This study’s findings will be provided to you, if you wish.

1. **What will happen to my sample after it has been tested?**

*[If appropriate]*: Your sample will only be used for the purpose of this research study. The blood or tissue sample/s you provide during the study will be destroyed at the completion of the study, although some samples may be kept if required under the laboratory’s accreditation standards.

[*If appropriate*] We would like to store this tissue for future use. This is explained further in the attached information sheet on storing or ‘banking’ tissue.

1. **Will I be able to withdraw my sample if I want to?**

It may not be appropriate in all circumstances to return your sample to you, for example where this may pose a risk of infection. However, where this can be done,

[*If appropriate*]: You may contact your study doctor at any time and request that your sample be *destroyed/returned*.

[*If appropriate*]: You may contact your study doctor at any time up until [*insert date*] and request that your sample be *destroyed/returned*. However, after that time it will not be possible to destroy/return your sample because [*insert reason*].

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

The study is being sponsored by … [*name of commercial or other entity - include a statement about any duality or conflict of interest that any investigators may have*].

1. Will drug or biotechnology companies be able to use my sample for profit in the future?

[*If appropriate*]: There is the possibility of this research resulting in commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your blood or tissue sample.

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 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote [*HREC project number*].

[*Add for Multi-site research*] 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*]

1. **[If appropriate]: ‘What if I don’t want to know the results?**

 It is entirely your decision as to whether or not you decide to be told the results. This will not affect the treatment you receive now or in the future.

1. [If appropriate]: ‘What if the results are relevant to members of my family or other relatives?

Your results may be relevant to the health or well-being of family members or other relatives, for example because:

the results indicate an inherited disease or other condition which might affect them,

AND/OR

the results have the potential to detect that either you or a family member are not the parent of a child, as presumed.

If this is the case, your results will only be disclosed to those family members or relatives with your consent.

Depending on your results, it might be appropriate to approach your relative/s to join the study. However, this will not occur without your consent.

1. **[If this form is not being used in conjunction with a main PISCF insert the following]: ‘What happens if I suffer injury or complications as a result of the study?**

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

*[If applicable]* The parties to this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. The fact that the parties have agreed to abide by these guidelines in respect of the clinical trial does not affect your rights to pursue a legal remedy in respect of any injury you may suffer as a result of participation. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee.

**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 as a subject 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*)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of witness Please PRINT name Date**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

# 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]

## WITHDRAWAL 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 Principle Investigator).**