[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]*

CLINICAL TRIAL/CLINICAL RESEARCH

(EXCLUDING GENETIC TESTING AND COLLECTION/STORAGE 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 [*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*].

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

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

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 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.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

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 trial, for example…*] However, it may not be possible to withdraw your study samples or to withdraw your data from the study results if these have already had your identifying details removed.

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

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

This study will be conducted over XX *days/weeks/months/years*.

[*If appropriate*] The treatment being investigated in this study differs from the standard treatment offered in this institution because of

…its’ use of drug *NEWDRUG* which is in early stage of development. OR

…its’ use of *OLDDRUG*, an agent that has been recently found to have new properties that may be useful in treating [*insert disease/condition*]. OR

…its’ use of the technique *NEWTECH.*

[*If appropriate, include the following definitions*:

‘Randomised trial’: Sometimes doctors don’t know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives.

‘Blind trial’:In a “blind trial” the study participants do not know which treatment group they are in. If the trial is “double blind”, neither the doctor nor the study participant knows which treatment the participant is receiving (although, if the doctor needs to find out, he/she can do so).

‘Placebo’: A placebo is a treatment that looks like the genuine medicine but contains no active ingredient.]

If you agree to participate in this trial, you will then be asked to …[*for one study procedure*] OR…

If you agree to participate in this trial, you will then be asked to undergo the following procedures: [*list multiple procedures as numbered or bullet points and give them in the order they will happen*].

[*If appropriate: definition of blood sampling]* Samples of blood taken from a vein will be required. The amount of blood taken will be equivalent to [*insert number*] of millilitres (or [*insert number*] of teaspoons) taken on [*insert number*] occasions.

*[If appropriate]* Participating in the trial will require some restrictions on your lifestyle during the study. These include…[*insert*].

[*If appropriate*] In addition, the researchers would like to have access to your medical record to obtain information relevant to the study.

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*].

[*If appropriate*] All of the money being paid by the sponsor to run the trial will be deposited into an account managed by [*insert hospital/Area Health Service*]. No money is paid directly to individual researchers.

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

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

[*Provide information on inconvenience, reasonably foreseeable risks, discomforts or side effects that may occur, their likelihood in terms of 1 in 10, 1 in 100 etc or %, potential severity and duration (where possible)*]

There may also be risks associated with this trial that are presently unknown or unforeseeable.

[*Complete this section carefully. In certain circumstances e.g. terminal illness, elderly population* *its use would be inappropriate.]* It is important that women participating in this study are not pregnant and do not become pregnant during the study as the study [*drugs, procedures*] may damage an unborn baby.

The effect of the study [*drugs/procedures*] on an unborn baby is unknown. If you are a woman of childbearing age and there is any possibility that you are pregnant, the researchers will need to perform a urine pregnancy test before you start in the study.

If necessary, you should use reliable contraception (such as oral or implanted contraception, an IUD or have had a tubal ligation if you are female, or condoms if you are male) during the course of the study. If at any time you think you, or your sexual partner, may be pregnant it is important to let the researchers know immediately.

1. **What are the alternatives to participation?**

*[For therapeutic research the participant should be told what other treatments are available and how the research differs from standard treatment]*

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include *[give examples of standard treatment]*. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

1. **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.

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. You will be reimbursed for your time and reasonable travel expenses to the amount of [s*tate maximum amount of reimbursement, if applicable*] [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.

**[\*See NSW Health Standard Patient Information Sheet for ‘tissue banking’]**

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

Of the people treating you, only [***insert details of*** *those named above or necessary others eg all nursing staff involved in your care*] will know whether or not you are participating in this study. 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. Results of the study will be provided to you, if you wish.

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

[*As appropriate*] The [*drug/procedure*] will not be available after the study finishes. The treatment available will be…. OR….

You may be able to continue [*drug/procedure*] following completion of this study if it found to be of benefit to you.

This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

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*]

**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. I,................................................................................................................. of................................................................................................................

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

2. 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.

3. 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.

4. 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).***

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

6. 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.

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

Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, 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]

## 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 Principal Investigator).**