APPLICATION PROCEDURES TO
SSWAHS HUMAN RESEARCH ETHICS COMMITTEE
(Western Zone)

Once the application and Site Specific Assessment Form has been certified by the General Manager(s) and relevant signatories, you should provide the Human Research Ethics Committee (Western Zone) with the ORIGINAL application plus 18 copies of the following documents in this order (DO NOT STAPLE OR BIND THE **ORIGINAL**)

- The application Form
- The Subject Information Sheet (printed on SSWAHS or hospital letterhead)
- The Consent Form (printed on SSWAHS or hospital letterhead)

Also required are

- if the project involves the use of a questionnaire, advertisement or letters of invitation please provide 3 separate copies
- three copies of project protocol and any supporting references
- one copy of each Investigator's Curriculum Vitae

- One copy of the Site Specific Assessment Form
- original CTN form or CTX form (where applicable)
- two original Medicines Australia Forms of Indemnity signed by representative of the sponsor (where applicable)

by the relevant closing date, to:-

Postal Address:
Mrs Jennie Grech
Manager, Research and Ethics Office
SSWAHS Human Research Ethics Committee (Western Zone)
Locked Bag 7017
LIVERPOOL BC 1871

Delivery Address:
Acacia Cottage
Liverpool Hospital.
(Adjacent to the Multi-storey carpark)

If any further information or assistance is required, please contact the Ethics Secretariat at the address shown above, or telephone (02) 9828 6552. The fax number for the Secretariat is (02) 9828 6551 and Email address is jennie.grech@sswahs.nsw.gov.au

[Use SSWAHS
letterhead paper for page 1]

SUBJECT INFORMATION STATEMENT

(*Title of project*: .....)

[Subject selection and purpose of study]

You *(ie the subject)* are invited to participate in a study of *(state what is being studied)*. We *(ie the investigators)* hope to learn *(state what the study is designed to discover or establish)*. You were selected as a possible participant in this study because *(state why the subject was selected)*.

[Description of study and risks]

If you decide to participate, we *(or: Dr..... and associate(s)* will *(describe in simple language the procedures to be followed, including the use of placebos, their purpose(s), how long the procedures will take, and their frequency)*.

(Describe the discomforts and inconveniences reasonably to be expected. An estimate of the total time required must be included.)

(Describe the possible risks reasonably to be expected. Describe any benefits to the subject reasonably to be expected. If benefits are mentioned, add:

We cannot and do not guarantee or promise that you will receive any benefits from this study.

(Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.)

[Confidentiality and disclosure of information]

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or except as required by law. If you give us your permission by signing this document, we plan to *discuss/publish* the results *(state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure).* In any publication, information will be provided in such a way that you cannot be identified(include a footer which identifies the version and date of the PIS)

(*Title of project*: .....)

[Financial Costs]

It is not anticipated that you will incur any additional costs if you participate in this study. You will receive the study drugs free of charge. There is no cost to you for any tests specifically related to this research study.

You will **not** receive any payment for participation in this study. *(If the subject will receive remuneration, describe the amount or nature. If there is a possibility of additional costs to the subject because of participation, describe it.)*

[Drug Company name] will

- Supply the study drugs free of charge for all eligible patients registered in this study and
- Provide a payment to [name of department and health service] for each eligible patient registered in this study

The monies received will be used to cover the costs of:

- [list what the monies will be used for, ie salaries, equipment, data management of the study, tests and assessments associated with the study]

[Your consent]

Your decision whether or not to participate will not prejudice your present or future treatment or your relationship with Sydney South West Area Health Service or any other institution cooperating in this study or any person treating you. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions later, your study doctor, Dr ..... *(provide a phone number)* will be happy to answer them.

You are making a decision whether or not to participate. Your signature on the consent form indicates that, having read the information provided above, you have decided to participate.

Complaints may be directed to the Ethics Secretariat (Western Zone), SSWAHS Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 6552, fax 9828 6551, email jennie.grech@sswahs.nsw.gov.au).

You will be given a copy of this form to keep.

[Use SSWAHS letterhead paper for page 1]

CONSENT FORM

(*Title of project*: .....)

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

1. I, ... of .....
......, aged .....years,
agree to participate as a subject in the study described in the subject information statement set out above *(or: attached to this form).*

2. I acknowledge that I have read the Subject 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 to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation. I have received satisfactory answers to any questions that I have asked.

4. My decision whether or not to participate will not prejudice my present or future treatment or my relationship with Sydney South West Area Health Service or any other institution cooperating in this study or any person treating me. If I decide to participate, I am free to withdraw my consent and to discontinue my participation at any time without prejudice.

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 the study doctor, Dr .....on telephone....., who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Subject Information Statement.

Complaints may be directed to the Ethics Secretariat (Western Zone), Sydney South West Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 6552, fax 9828 6551, email jennie.grech@sswahs.nsw.gov.au).

Signature of subject _____ Signature of witness _____

Please PRINT name _____ Please PRINT name _____

Date _____ Date _____

Signature(s) of investigator(s) _____

Please PRINT Name _____

Date: _____

((include a footer which identifies the version and date of the Consent Form)

[Use SSWAHS letterhead paper for page 1]

PARENTAL (OR GUARDIAN) INFORMATION STATEMENT

(*Title of project*: .....)

[Subject selection and purpose of study]

You are invited to permit your child to participate in a study of *(state what is being studied).* We *(ie the investigators)* hope to learn *(state what the study is designed to discover or establish)*. Your child was selected as a possible participant in this study because *(state why the child was selected)*.

[Description of study and risks]

If you decide to permit your child to participate, we *(or Dr ..... and associate/s)* will *(describe in simple language the procedures, including the use of placebos, to be followed, their purposes, how long they will take, and their frequency).*

(Describe the discomforts and inconveniences reasonably to be expected. An estimate of the total time required must be included.)

(Describe the possible risks reasonably to be expected. Describe any benefits to the child reasonably to be expected. If benefits are mentioned, add:

We cannot and do not guarantee or promise that your child will receive any benefits from the study.

(Describe appropriate alternative procedures that might be advantageous to the child, if any. Any standard treatment that is being withheld must be disclosed).

[Confidentiality and disclosure of information and Recompense to subjects]

Any information that is obtained in connection with this study and that can be identified with you or your child will remain confidential and will be disclosed only with your permission or except as required by law. If you give us your permission by signing this document, we plan to *discuss/publish* the results *(state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure). In any publication, information will be presented in such a way that you or your child will not be able to be identified.*

[Financial Costs]

It is not anticipated that you will incur any additional costs if you participate in this study. You will receive the study drugs free of charge. There is no cost to you for any tests specifically related to this research study.

You will **not** receive any payment for participation in this study. *(If the child's parent will receive remuneration, describe the amount or nature. If there is a possibility of additional costs to the parent because of participation, describe it.)*

[Drug Company name] will

- Supply the study drugs free of charge for all eligible patients registered in this study and
- Provide a payment to [name of department and health service] for each eligible patient registered in this study

You will be given a copy of this form to keep.

(include a footer which identifies the version and date of the PIS) Page 1 of 2

The monies received will be used to cover the costs of:

- [list what the monies will be used for, ie salaries, equipment, data management of the study, tests and assessments associated with the study]

[Your consent]

Your decision whether to not to permit your child to participate will not prejudice you or your child's present or future treatment or your relationship with Sydney South West Area Health Service or any other institution cooperating in this study or any person treating you. If you decide to permit your child to participate, you are free to withdraw your consent and to discontinue your child's participation at any time without prejudice.

If you have any questions, we expect you to ask us. If you have any additional questions later, your study doctor, Dr ..... *(provide a phone number)* will be happy to answer them.

You are making a decision whether or not to permit your child to participate. Your signature on the consent form indicates that, having read the information provided above, you have decided to permit your child to participate.

Complaints may be directed to the Ethics Secretariat (Western Zone), Sydney South West Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 6552, fax 9828 6551, email jennie.grech@sswahs.nsw.gov.au).

[Use SSWAHS letterhead paper for page 1]

PARENTAL (OR GUARDIAN) CONSENT FORM

(*Title of project*: .....)

1. I, ... of ...., agree to permit ....., who is aged .....years, to participate as a subject in the study described in the Parental Information Statement set out above *(or attached to this form).*
2. I acknowledge that I have read the Information Statement, which explains 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 to ask any questions relating to any possible physical and mental harm the child might suffer as a result of participation. I have received satisfactory answers to any questions that I have asked.
4. I understand that I can withdraw the child from the study at any time without prejudice to my or the child's relationship to the Sydney South West Area Health Service *(and the .....Hospital).*
5. I agree that research data gathered from the results of the study may be published, provided that neither I nor the child can be identified.
6. I understand that if I have any questions relating to the child's participation in this research, I may contact the study doctor, Dr ..... on telephone ....., who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Information Statement.

Complaints may be directed to the Ethics Secretariat (Western Zone), Sydney South West Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 6552, fax 9828 6551, email jennie.grech@sswahs.nsw.gov.au).

Signature of parent/guardian	Signature of witness
_____	_____
Please PRINT name	Please PRINT name
_____	_____
Date	Nature of Witness
_____	_____

Signature(s) of investigator(s)

_____

Please PRINT Name

_____

(include a footer which identifies the version and date of the Consent Form)

[Use SSWAHS letterhead paper for page 1]

PERSON RESPONSIBLE CONSENT FORM

(*Title of project*: .....)

I _____ have been given information about the abovementioned trial and agree that [Name of participant] _____ can participate as a subject in the study described in the patient information statement.

I acknowledge that I have read the Patient Information Statement, which explains why [name of participant] _____ has been selected, the aims of the study and the nature and the possible risks of investigation, and the statement has been explained to me to my satisfaction.

Before signing this Consent Form, I have been given the opportunity to ask any questions relating to any possible physical and mental that that [name of participant] _____ might suffer as a result of his/her participation, I have received satisfactory answers to any question that I have asked.

My decision whether or not [name of participant] _____ participates will not prejudice his/her present or future treatment or his/her relationship with South Western Sydney Area Health Service or any other institution co-operating in this study or any person treating him/her. If [name of participant] _____ participates, I am free to withdraw my consent and to discontinue his/her participation at any time without prejudice.

I agree that research gathered from the results of the study may be published, provided that [name of participant] _____ cannot be identified.

I understood that if I have any questions relating to [name of participant] _____ participation in this research, I may contact the study doctor who will be happy to answer them.

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

Signature of Person Responsible	Signature of witness
_____	_____
Please PRINT name	Please PRINT name
_____	_____
Date	Nature of Witness
_____	_____

Signature(s) of investigator(s)

_____

Please PRINT Name

_____

(include a footer which identifies the version and date of the Consent Form)

Sample 5
Project No:.....

CONSENT FOR COLLECTION, STORAGE AND TESTING OF HUMAN TISSUE FOR RESEARCH

You have been invited to participate in research which could involve the collection, storage and testing of blood, other tissue or DNA.

DNA is an abbreviation for deoxyribonucleic acid, the name of the chemical compound from which genes and chromosomes are made.

This research has been approved by the SSWAHSHuman Research Ethics Committee (Western Zone) at their meeting dated ??/??/??.

Page 2 is for your consent to the collection and testing of this genetic material. This form has been designed to ensure your consent is on an informed basis. Please read and consider each section. Below are some questions you may wish to ask the Researcher after you have read the information provided and before you consent to participate in the research project.

- What do you think you might find out in this research?
- Will I be able to get my results?
- Who else will get a copy of my results?
- If I choose to find out the results, what will this mean to me?
- If I agree to participate what arrangements have been made for my independent counselling and who is the independent counsellor?
- How might the results affect my family?
- If I choose to get the results, how long will it be before I get them?
- If I choose to get the results, who will help me to understand what they mean for me and my family?
- What will happen to my specimen or sample? Will it be used in other studies?
- Will my results have any effect upon my job, my being able to get insurance, or my status in legal matters?
- What will happen if this research leads to the manufacture of commercial products?
- What is meant by 'identifiable', 'potentially identifiable' and 'deidentifiable' information
- What happens to the information already collected if I withdraw my consent?

(include a footer which identifies the version and date of the Consent)

CONSENT FOR COLLECTION, STORAGE AND TESTING OF HUMAN TISSUE FOR RESEARCH

Testing Centre	MRN (or subject number)

Research Subject		Parent or Guardian (research subject under age or unable to consent)	
Given Names	Surname	Given Names	Surname
Address		Address if different from subject	
City/Suburb	Postcode	City/Suburb	Postcode
Telephone		Relationship to subject	Telephone

I understand and consent to the following as indicated that;

- My sample of tissue/blood/DNA will be used in a research study entitled

_____

And that my sample (the following two sections are to be explained to the patient by the Study doctor/nurse and completed ensuring that the patient fully understands)

1.	Will be destroyed at the completion of this study	Yes❑	No❑
2.	May be used in research testing of DNA	Yes❑	No❑
3.	May reveal non-paternity or non-maternity	Yes❑	No❑
4.	Will be destroyed if I withdraw my consent	Yes❑	No❑
5.	Information will be stored in		
	➢ Identifiable form	Yes❑	No❑
	➢ Potentially identifiable form (coded)	Yes❑	No❑
	➢ De-identifiable form (anonymous)	Yes❑	No❑
6.	May be stored for future research related to this study with my consent	Yes❑	No❑
7.	May be stored for future research unrelated to this study with my consent	Yes❑	No❑

And if possible:

8.	I wish to receive results of this study	Yes❑	No❑
9.	After counselling I wish to receive my personal results	Yes❑	No❑
10.	I wish my attending doctor to be advised if the study produces information which could be of value to me or my family	Yes❑	No❑
11.	I wish to know if there is further research being carried out on my tissue	Yes❑	No❑

I also understand that identifying genetic information will not be released to a third party, including family members without my written consent or that of a person responsible at law on my behalf.

NOTE: If tissue/blood/DNA is stored it may not remain in a suitable state for testing.

_____ (insert name of Doctor/Health Professional) has explained to me the consequences and procedures involved in the collection, storage and testing of the tissue/blood/DNA and I have had the opportunity to ask questions. I am satisfied with the explanation and the answers to my questions.

_____ _____

Signature of Research Subject/Guardian Date

_____ _____

Witness Date