



Health
South Eastern Sydney
Local Health District

HEALTH SCIENCE ALLIANCE BIOBANK

Participant Information and Consent Form

Version 1.4, dated 1 June 2012

This consent form is 7 pages long. Please ensure that you have all the pages.

The Health Science Alliance Biobank is a collaboration between the South Eastern Area Laboratory Services (SEALS) and the Lowy Biorepository.

1. Request

We ask that you consider giving your permission for collection of your specimens and associated clinical data for storage in the Health Science Alliance (HSA) Biobank. Your specimens would be stored for possible use in future research.

This participant information sheet contains detailed information about the HSA Biobank. The purpose of this document is to explain to you as openly and clearly as possible all the aspects of the Biobank before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker.

Once you understand what the Biobank is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the Biobank. You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. 'What kind of samples will be taken, and how?'

You have been invited to donate tissue samples and clinical data for storage in a Biobank as you have recently undergone surgery to remove some tissue from your body. Alternatively, you may have had some peritoneal or pleural fluid removed. This tissue and/or fluid has been removed as part of your routine clinical management. A small sample of tissue and/or fluid will be collected from the removed specimen and will be stored for use in future research.

A blood sample will also be requested and stored. Approximately 10mLs of blood (two teaspoons) will be required. Collection of this blood will occur during routine



blood collections so you will not be required to have any additional procedures. If we are unable to obtain a blood sample we may ask you for a spit sample or mouth swab instead. The procedure required to obtain a spit sample or mouth swab will be explained to you by the nurse. You will experience minimal discomfort or inconvenience as a consequence of these tests.

We also request access to information from your medical records relating to you, your operation and diagnosis. We will access and link data from the following sources containing information about your health, medication and treatment:

- Hospital, pathology, emergency department records;
- State databases, including the Admitted Patients Data Collection; Registry of Births, Deaths and Marriages; ABS Mortality Data; the NSW Cancer Registry and The 45 and Up Study;
- Medicare Benefits Scheme records (i.e. your visits to health professionals) and the Pharmaceutical Benefits Scheme (i.e. your use of prescription medicines);

3. 'Will the samples be identifiable as mine after they are stored?'

Yes, samples will be identifiable as yours. However only the HSA Biobank owner, the Biobank manager, the consenting nurse and the person collecting your specimens will have access to your identifiable data. In addition, senior medical researchers may be provided with your identifying data so that they may obtain clinical data about you that is relevant to their particular research study. This will only occur where the senior medical researchers have obtained approval for this from a Human Research Ethics Committee. Once you have consented to join the HSA Biobank your data will be entered into database specifically designed to collect and store biobank information. Your stored samples will automatically be given unique identification codes that will allow them to be linked to your data. We will maintain your confidentiality by only allowing other researchers access to your coded samples i.e. apart from the people mentioned above, no researchers will have access to your identity.

4. 'What will happen to my samples?'

Your samples and your health data will be stored in the Lowy Biorepository located at the University of NSW, Kensington Sydney. Your samples will not necessarily be used immediately; we will store them until they are required. Your samples will be stored for potential, and as yet unspecified, research in the future. Future research will focus on cancer and will include, but not be limited to, its prevention, diagnosis, treatment, genetics, demographics and controlled clinical trials. Any research proposal requesting access will only be considered if it has been approved by an accredited Human Research Ethics Committee. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in research.



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5. 'How will I know if my samples are being used in the future?'

If you agree to your samples being stored for future research, they will only be used for research projects in the future that have the approval of a Human Research Ethics Committee. You will not be contacted when your samples are used, however you can obtain information on future research conducted on samples stored in the HSA Biobank via the Lowy Biorepository website.

Any research findings from these future projects will be published in peer-reviewed journals and presented at conferences and other professional forums. In any publication, information will be provided in such a way that you cannot be identified.

6. 'Who will have access to my samples once they have been stored?'

The custodians charged with ensuring appropriate standards are met in storing and managing the tissue bank will have access to your sample. Researchers involved in research approved by a Human Research Ethics Committee may also have access to your samples. Your samples may also be released if ordered by law.

7. 'Will drug or biotechnology companies be able to use my samples for profit in the future?'

There is the possibility that research involving your blood or tissue samples may result in commercially viable technology or treatments. You will not however be able to claim financial benefit from any discoveries arising from the use of your samples.

8. 'How long will my samples be stored?'

Your samples will be stored until they are required for use in research.

9. 'Will I be able to get my samples back if I change my mind once they have been stored in the Biobank?'

You may contact SEALS or the HSA Biobank any time after your samples were collected and request that the samples collected for the HSA Biobank and the data linked to your samples be destroyed. Your decision to withdraw your samples will not affect any medical treatment or care you receive now or in the future.

10. 'Who should I contact if I have concerns about the conduct of the HSA Biobank?'

This Biobank has been approved by the South Eastern Sydney Local Health District - Northern Sector Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this Biobank 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 <mailto:ethicsnhn@sesiahs.health.nsw.gov.au> and quote reference number 11/160.



The conduct of this Biobank at the Prince of Wales Hospital, Prince of Wales Private Hospital and Royal Women's Hospital has been authorised by the South Eastern Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer of the South Eastern Sydney Local Health District – Northern Sector, Prince of Wales Hospital, Randwick NSW 2031; telephone 02 9382 3587, or email <mailto:ethicsnhn@sesiahs.health.nsw.gov.au>.

11. 'What happens if I suffer injury or complications as a result of the Biobank?'

If you suffer any injuries or complications as a result of the Biobank, you should contact your 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 Biobank. Compensation may be available if your injury or complication is caused by the negligence of any of the parties involved. 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.

The parties to this Biobank 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 Biobank.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**



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HEALTH SCIENCE ALLIANCE BIOBANK

Prince of Wales Hospital, Prince of Wales Private Hospital and the Royal Women's Hospital

CONSENT FORM

1. I,.....
of.....
agree to participate as a subject in the HSA Biobank described in the participant information statement set out above.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected to partake in the Biobank, 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 Biobank at any time without prejudice to my relationship to the Prince of Wales Hospital, Prince of Wales Private Hospital and the Royal Women's Hospital.
5. I agree that research data gathered from the results of the Biobank may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in the Biobank, I may contact Prof Robyn Ward on telephone 02 9382 8870 who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.



Please read carefully and tick either YES or NO if you wish to only partake in certain elements of the HSA Biobank

1. I give my permission for the collection of my tissue/fluid samples and their use in future research Yes No
2. I give permission for the collection of my blood and/or saliva samples and their use in future research Yes No
3. I give my permission for the collection of my clinical hospital data and its use in future research Yes No
4. I give my permission for the linkage of data from other sources and its use in future research. Such data includes the Admitted Patients Data Collection; Emergency Department Information System; Registry of Births, Deaths and Marriages; ABS Mortality Data; the NSW Cancer Registry and The 45 and Up Study. Yes No

Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District - Northern Sector, Prince of Wales Hospital, Randwick NSW 2031 Australia. Phone (02) 9382 3587, Fax (02) 9382 2813, or [email ethicsnhn@sesiahs.health.nsw.gov.au](mailto:ethicsnhn@sesiahs.health.nsw.gov.au).

Signature of participant

Please PRINT name

Date

Signature of witness

Please PRINT name

Date

Signature of investigator

Please PRINT name

Date



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**Prince of Wales Hospital, Prince of Wales Private Hospital
and the Royal Women's Hospital**

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the HSA Biobank described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Prince of Wales Hospital, Prince of Wales Private Hospital or the Royal Woman's Hospital or my medical attendants.

Signature of participant

Please PRINT name

Date

The section for Revocation of Consent should be forwarded to:

Lowy Biorepository Manager
Lower Ground Floor
Lowy Research Centre
University of NSW
Kensington
NSW 2052