

The NSW CLEAR Study

Cancer, Lifestyle and EvaluAtion of Risk Study

Participant Information Sheet

Before you decide whether or not you wish to participate in The NSW CLEAR Study, it is important for you to understand why the Study is being done and what it will involve. Please take the time to read the following information carefully and contact us if you have any questions.

1. Invitation

You are invited to participate in the NSW CLEAR Study, which will be used by researchers to carry out investigations into the causes and consequences of cancer. Participation involves signing a consent form, completing one questionnaire (which takes 30-40 minutes to complete), and the option to provide a blood sample.

You can participate in the CLEAR Study if you have been diagnosed with cancer in the last 18 months, are 18 years or older, and a resident of NSW. You may also participate if you have never had cancer yourself, if your spouse or partner has cancer and participated in the CLEAR Study.

We apologise in advance if you receive more than one invitation to participate in the CLEAR Study as we use various ways to identify potential participants.

2. Who is conducting the study?

The Study is being conducted by the Cancer Epidemiology Research Unit (CERU) at the Cancer Council NSW (CCNSW) by the researchers listed below:

Name	Position	Department
A/Prof Freddy Sitas	Director	CCNSW Cancer Epidemiology Research Unit
Prof Dianne O'Connell	Senior Epidemiologist	CCNSW Cancer Epidemiology Research Unit
A/Prof Karen Canfell	Senior Research Fellow	CCNSW Cancer Epidemiology Research Unit
Prof Michael Barton	Research Director	Collaboration for Cancer Outcomes, Research and Evaluation Liverpool Health Service
Prof Emily Banks	NHMRC Senior Research Fellow	National Centre for Epidemiology and Population Health, Australian National University

3. What is the purpose of the Study?

By contributing information in a questionnaire and providing a blood sample you will be providing important information to build a data and biobank so that future researchers can investigate the causes and consequences of cancer, and possibly what factors may protect a person from getting cancer. We will do this by collecting information from participants with and without cancer. The best way to understand the causes of such a complex disease as cancer is to collect, examine and compare detailed information from many people with a wide variety of personal, family and cultural backgrounds.

4. What does participation involve?

Participation involves completing a consent form and questionnaire. You will also be asked to provide a small blood sample, which is optional. In the consent form we ask your permission to access health related information about you that is held by other health related organizations (see table on next page) and request your consent to contact you for follow up research for this Study. Participation in future studies will be entirely voluntary, and you may change your mind at any time. If you have cancer, we also request permission to obtain a tissue sample held by your pathologist. By linking and comparing all this information together, researchers will be able to gain a greater understanding of factors contributing to cancer.

4.1 First step: Consent Form

The first thing to do is to complete the Study consent form. This document gives us permission to collect, store, and link your information, and optionally collect and store your blood and tissue samples.

4.2 Second step: Questionnaire

After completing the consent form, you will need to fill in the questionnaire which typically takes about 30 - 40 minutes. The questionnaire asks about medical history, lifestyle, diet, family and use of medications. When you've finished the questionnaire, simply return it along with the consent form. You can use the postage paid, pre-addressed envelope provided.

4.3 Third step: Blood and Tissue Samples (Optional)

We invite you to provide us with a blood sample (about 3 tablespoons) which will be stored at the Study biobank (a cold storage facility) for use in future research. If you had cancer, we also ask that you to give us permission to have a part of your cancer tissue sample, which has already been taken during your diagnosis or surgery.

4.3.1 How will the blood and tissue sample be taken?

If you agree in the consent form to give a blood sample, then we will send you a blood collection form. At a convenient time, you can take this form to a local blood collection centre. A list of nearby centres is provided on the form. The sample will be transported directly to us. There is no cost to you.

You may experience some mild discomfort and minor bruising or swelling at the site where the blood sample is collected.

If you agree to let us collect a tissue sample of your cancer, just indicate this on the consent form. You won't need to have another sample taken. Instead, we will contact the facility where your surgery or diagnosis was done, and ask them for a tissue sample.

4.3.2 What will happen to my blood and tissue sample?

Developments in laboratory knowledge about cancer regularly open up new research ideas. By storing your blood and/or tissue samples indefinitely (until it is all used) we can enable researchers to make the best use of new knowledge in future research.

Usually only a very small amount of blood or tissue is required, and therefore the overall storage time may last for several decades.

4.3.3 How will I know if my samples are being used in the future?

If you agree to your blood / tissue sample/s being stored for future research, they may be used for research projects in the future with the approval of a Human Research Ethics Committee. The Human Research Ethics Committee will determine whether, or not, your consent should be obtained at that time for a particular research project. If your consent is needed, then you will be contacted with information on the follow up research Study.

4.3.4 Who will have access to my blood and tissue samples?

Approved researchers and staff managing the Study will have access to your sample. Researchers handling your sample will only do so in studies that have been approved by a Human Research Ethics Committee.

5. Data Linkage

An important aspect of the Study is observing your health over time. With your permission we will access and link information from your questionnaire with a number of other sources as listed in the table overleaf for information about your past, current and future health.

The information from these health datasets will only be linked with the information from the Study if you consent to this, and after Human Research Ethics Committee approvals for access and linkage to each of the datasets has been obtained.

6. What are the required and optional parts of the Study?

The information that we would collect about you and the reason for collecting it is shown in the table below. Some aspects of the Study are required and some are optional. You can let us know on the consent form if you agree to the optional parts.

Source	Reason	Required?
Documents		
Consent form	To allow the Study to collect and store data (and samples), to allow data linkages.	Yes
Questionnaire	To collect information about health and lifestyle	Yes
Samples		
Blood	To test for genes, viruses, bacteria and other factors	Optional
Tissue	To test for genes, viruses, bacteria and other factors	Optional
Data Linkage		
NSW Central Cancer Registry	To link medical history, cancer pathology, use of hospital services and confirm cancer status	Yes
Admitted Patient Data Collection	To link medical history, cancer pathology and use of hospital services	Yes
Australian Bureau of Statistics	To access information on the date and circumstances in case of death	Yes
State Registries of Births, Deaths, and Marriages and/ or National Death Index	To access information on the date and circumstances in case of death.	Yes
NSW Hereditary Cancer Registry	To access information about family history from this register.	Yes
The 45 and Up Study	To link your data with health information from the 45 and Up Study (if you participated in it)	Yes
Dentist	To link your data with dental records	Optional

7. Will Participating in the Study cost me anything?

Participation in this Study will not cost you anything

8. What happens with the results?

Your individual results will not be communicated to you. Results from any tests and analyses will be incorporated back into the CLEAR Study for use in future research.

In any publication, information will be provided in such a way that you cannot be identified. Any results from publications will be reported on the Study website at www.clearstudy.org.au.

9. What if I don't want to participate or change my mind later?

Participation in this Study is voluntary. It is completely up to you whether or not you want to take part. Whatever your decision, it will not affect your relationship with the Cancer Council NSW, or your health care provider.

If you change your mind and decide not to be in the Study any more, just call 1 800 500 894 or complete and return the Revocation of Consent form found on the last page of this Participant Information Sheet. You can ask to have all your information and samples destroyed. For safety reasons we are unable to return your sample to you. Please note that if certain research has already been carried out using your data before you contact us, then it will not be possible to remove your data from such analyses. However, your data will not be available for any future research.

10. How will my privacy be protected?

Your privacy is carefully protected at all times. All information and blood samples provided to the Study are protected by Commonwealth and State privacy legislation and guidelines, including the Health Records and Information Privacy Act.

Our commitment to providing a high standard in handling personal information includes:

- Working with St Vincent's Human Research Ethics Committee which is responsible for overseeing the conduct of the Study, NSW Population & Health Services Research Ethics Committee for granting access to data, and other relevant ethics committees.
- Ensuring information is only used for health research and the purposes described in this Participant Information Sheet.
- Ensuring your identifying information, such as name and address, is removed and stored separately upon initial processing and thereafter.
- Data linkages will be conducted under strict privacy and confidentiality processes, as approved by the relevant Ethics Committee.
- Ensuring information is not released in a way that would allow an individual to be identified, except as required by law.

11. Who should I contact if I have concerns about the conduct of the Study?

If you have a complaint or would like to speak to someone who is not involved in the Study please contact the Executive Officer at St Vincent's Hospital Human Research Ethics Committee on (02) 8382 2075 and let them know its about the CLEAR Study, Reference number: #07/072.

Cancer Council NSW which has sent you the initial invitation letter, has been authorised by the Cancer Council NSW to be part of the Study. If you have concerns or complaints about the Study, you may also contact the Research Governance Officer Ms Kate Whittaker on 02 9334 1993 and let them know it is about the CLEAR Study #200.

12. What should I do now?

Once you have read all the information and would like to join the Study, please fill in the consent form and the questionnaire as soon as you have the time and send them back in the reply paid envelope provided.

If you are not sure, please feel free to call the CLEAR call centre on 1800 500 894 to talk about it.

If you definitely don't want to participate in the Study you have the option to do nothing, or complete the Opt Out Form which will help us understand why you've chosen not to participate.

13. If you would like further information about the Study please contact us by:

Post: CLEAR Reply Paid 79819, Potts Point NSW 1335
Phone: 1 800 500 894
(Monday to Friday, 8:00am – 5:00pm)
Email: CLEAR@nswcc.org.au
Website: www.clearstudy.org.au
Fax: (02) 8302 3550

Thank you for your time and consideration.

Cancer Council NSW

The NSW Cancer, Lifestyle and Evaluation of Risk (CLEAR) Study

Revocation of Consent

SEND THIS FORM TO US IF YOU DO NOT WANT TO PARTICIPATE IN THE STUDY ANYMORE

I hereby wish to WITHDRAW my consent to participate in the CLEAR Study. I understand my information will be deleted not to be used in the future. Furthermore, I understand that any samples held by the Study will be destroyed.

I also understand that such withdrawal will not jeopardise the treatment I receive from my health fund, hospital, clinic, doctor or health worker that helped to recruit me in the Study, or my relationship with Cancer Council NSW.

Signature: _____ Date: / /

Please PRINT name: _____

The section for Revocation of Consent should be forwarded to:

CLEAR
Locked Mail Bag 79819
Potts Point NSW 1335

Please note: Keep this form so that you may use it, if you wish to discontinue as a study participant.