

# Participant Information Sheet

## Australian Cancer Risk Study: Genomic risk factors for cancer and cancer risk prediction in the 45 and Up Study

This research project is in addition to the main 45 and Up Study. Participation is voluntary. Participation in this project does not change your involvement in the main 45 and Up Study. Information collected by this research project will become part of the 45 and Up Study in future.

### What is the purpose of this research project?

We are conducting a medical research study to identify how a person's DNA – their genetic make-up – influences their risk of developing cancer.

One in two Australians will develop cancer by the age of 85. Genetic factors play an important role for each of the four most common cancers (breast, colorectal and prostate cancers, and melanoma). In the future, genetic information could be used to predict cancer risk and to improve the early detection of these common cancers.

This research project aims to develop and test cancer risk prediction tools for the Australian population by combining genetic, lifestyle, and health information. These tools may help us to prevent and treat cancer more effectively.

### Who is conducting this research project?

This research is being led by Professor Anne Cust and Dr Julia Steinberg at the Daffodil Centre, a joint venture between the University of Sydney and Cancer Council NSW. The research is being done in collaboration with the Sax Institute, and the research study team includes world-leading researchers, policy makers and consumers, from a range of Australian institutions including the QIMR Berghofer Medical Research Institute and the Centre for Population Genomics (a collaboration between the Garvan Institute and the Murdoch Children's Research Institute). More details about the

research team can be found here:

<https://daffodilcentre.org/>

This project has been funded through the Medical Research Future Fund project *Genomic risk prediction and risk-tailored screening and early detection for common cancers* to help optimise future cancer screening and early detection and improve the health of Australians.

### Why do you want me to take part?

As a participant in the 45 and Up Study, you have previously agreed to be contacted about health research projects.

We are inviting some 45 and Up Study participants with a previous cancer diagnosis, as well as some randomly selected Study participants, to take part in this project by providing a saliva (spit) sample. The saliva samples will enable us to identify genetic differences between people that are related to their risk of developing cancer. Your participation may help to develop better ways to prevent cancer or to detect it earlier, helping to prevent cancer deaths in the future.

### What does participation involve?

If you choose to take part in this research project, you will be asked to provide a saliva sample and consent to the sample (and the genetic information derived from it) being used for this research project, as well as future health or medical research studies approved by relevant human ethics committees. We will ask you to provide your name and contact details on the consent form, so that we can send you a saliva collection tube by post. When you receive

the tube, we will ask you to provide a small saliva sample (2mL, about half a teaspoon) and return it via a pre-paid post pack. Providing the sample typically takes about 5 minutes, and instructions will be sent to you with the saliva collection tube.

### **What are the benefits of this research project?**

There will be no immediate personal benefit to you from your participation in this research project. Participation will not cost you anything and you will not receive any payment. Your participation will contribute to our understanding of cancer risk and will help make cancer screening and early detection more effective in the future. Our goal is to produce evidence-based policy and clinical recommendations to reduce the burden of common cancers and help Australians live longer, healthier lives.

### **How will this project obtain my 'genetic make-up' and what will it be used for?**

Your saliva contains your DNA, a molecule that carries the genetic instructions for the development, functioning, and growth of cells and organisms. DNA is made up of units of information called genes.

When your saliva sample arrives at the laboratory, we will extract the DNA. The DNA will then be used to obtain a read-out of your genetic information. Your genetic information contains millions of small differences that make you unique compared to other people. By analysing the genetic information from thousands of people, we can determine which differences are either more or less common in people with cancer. When combined with other lifestyle and health information, this genetic information can be used to help predict cancer risk. Your genetic information may also be used indefinitely for future approved health and medical studies to answer new research questions.

### **Are there any risks if I participate?**

The project is very low risk to participants. **Currently in Australia**, genetic research **does not affect your ability to obtain private health insurance**. It is however possible that in the future, the fact that you have taken part in a study involving genetics might affect you or your

family if you want to take out a new health, disability, or life insurance policy. **We will not pass any information about you to anyone, including your family members, without your written permission unless obliged to by law.**

### **Can this project help determine my risk of cancer or other diseases?**

The technology used to identify the genetic information in this research project is very new, so our project cannot identify results of potential importance to your health. This means that your information will only be used for research purposes and **you will not be given any personal results from this project**. The nature of this research project means that the data are anonymised prior to analysis, so you cannot be identified in any research results.

It is possible that future research using your sample may result in new information about your risk of getting cancer or another disease. It is your choice whether or not you wish to be contacted by the 45 and Up Study if a future project finds some results relevant to your or your family's health. You can choose whether or not to be contacted on the consent form. **We will not contact you about any results without your permission.**

### **How will my privacy be protected?**

Protecting your personal information is extremely important to us. Signed paper consent forms will be scanned then shredded, and scanned and electronic consent forms will be saved on a password-protected computer server at the Sax Institute. Access to this information will be restricted to authorised personnel. Your name and contact details will be provided to a project-specific team at the QIMR Berghofer Medical Research Institute, for the sole purpose of providing you with a saliva collection kit. Once the saliva kit has been returned and the genetic information processed, these details will be deleted permanently.

**Your sample and genetic information will be stored securely, and they will be 'de-identified', i.e. assigned a random number so that they cannot be immediately identified as coming from you.** To obtain the genetic information from the DNA, we may send some of your DNA to another laboratory (which may be overseas), but only as approved by an

Australian ethics committee and with strict agreements in place to ensure data safety and security. Your DNA sample will only be labelled with a random number, not with your name or your personal information, and it will be transported along with samples from many other participants. The DNA sample sent to another laboratory will be destroyed after processing.

The combined dataset for this research project (including genetic data and existing lifestyle and health data from the 45 and Up Study) will be analysed within the Sax Institute's Secure Unified Research Environment (SURE), a world-class secure virtual computing platform. Access will be restricted to authorised researchers only.

The genetic information from this study and any remaining DNA sample will become part of the 45 and Up Study resource. Your genetic information and any remaining DNA sample will be stored indefinitely and combined with other information from the 45 and Up Study. Some of your de-identified genetic information (but not your name, personal details, lifestyle or health information) may eventually be put into an international genetics data repository for indefinite storage, so it could be used for future ethically approved research on cancer and/or other medical or health conditions. This information will continue to be valuable to researchers many years into the future.

**For all future projects, researchers will need approval from an ethics committee and the 45 and Up Study to access your genetic information or any remaining DNA sample. Your information and DNA sample will be de-identified (i.e. anonymised and assigned a random number only, so it is not directly linked to your identity or name), and researchers will not be able to identify you.**

Results from this research project and any future projects may be presented in scientific papers, or in scientific or public talks, but your identity

will not be revealed. Your data will be combined with the data from many other people for analysis. There will be no way of identifying you as a participant based on the scientific papers or talks.

### **How can I find out about the results of this research project?**

Our research will take several years, and it may be a long time before the results are available. Updates on the progress and findings of this research project will be included in the 45 and Up Study's regular participant newsletter and on the Sax Institute website and Facebook page. You can also contact the Study team at any time if you have any questions about this research project.

### **Can I withdraw from the research project?**

You can withdraw from this research project at any time by contacting the 45 and Up Study. This will not affect your participation in the wider 45 and Up Study, nor will it affect your future medical treatment. It may not be possible to destroy material that has already been processed or information that has already been used for research. The 45 and Up Study team can provide additional information regarding withdrawal if required.

### **Who can I contact if I have additional questions?**

Please call the Study Infoline on **1300 45 11 45**, or email [45andUp@saxinstitute.org.au](mailto:45andUp@saxinstitute.org.au)

### **Ethics approval and contact information**

This research project has been approved by the NSW Population and Health Services Research Ethics Committee reference: 2022UMB0401. Any person with concerns or complaints about the conduct of this research should contact the Ethics Coordinator on 02 8374 3610 or by email at [cinsw-ethics@health.nsw.gov.au](mailto:cinsw-ethics@health.nsw.gov.au)

# About the 45 and Up Study

The 45 and Up Study is the largest general population program of health-related research ever conducted in Australia. More than 267,000 people aged 45 and over are participating in the Study, and they are being followed over time through routine follow-up questionnaires and linkage to health and other records.

The 45 and Up Study has been approved by the University of New South Wales Research Ethics Committee.

Study participants have also given permission to be invited to participate in further research projects. Each of these research projects has been through a stringent review process prior to approval. **Participation in these research projects is optional.**

## Study governance

The 45 and Up Study is owned and managed by the Sax Institute in collaboration with major partner Cancer Council NSW and partners the Heart Foundation and the NSW Ministry of Health.

## About the Sax Institute

The Sax Institute is an independent, not-for-profit organisation that improves health and wellbeing by driving better use of evidence in policies, programs and services.

The Institute is a registered charity that works with governments, health organisations, research organisations and a network of experts nationwide to analyse policy problems and find the best evidence-based solutions. See [www.saxinstitute.org.au](http://www.saxinstitute.org.au) for more information.

## Contact the Sax Institute about the 45 and Up Study

For any questions, comments, or complaints about the 45 and Up Study or this research project, to withdraw consent for participation or for further communication, please contact us:

**Telephone:** 1300 45 11 45 (toll-free Study Infoline)

**Email:** [45andUp@saxinstitute.org.au](mailto:45andUp@saxinstitute.org.au)

**In writing to:** Dr Martin McNamara, Chief Investigator, 45 and Up Study, GPO Box 5289, Sydney NSW 2001

## Confidentiality

The 45 and Up Study, and any research projects associated with it, are bound by Commonwealth and State privacy legislation and guidelines: the *Privacy Act 1988* (Cth), *Health Records and Information Privacy Act 2002* (NSW), and the NSW Health Privacy Manual for Health Information. The 45 and Up Study has strict procedures and systems in place to safeguard participant confidentiality. The Study is also bound by strict scientific ethical accountability to the University of New South Wales:

Ethics Secretariat

University of New South Wales  
Sydney NSW 2052

**Telephone:** (02) 9385 6222

**Email:** [humanethics@unsw.edu.au](mailto:humanethics@unsw.edu.au)

**Thank you.** We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you.

This information sheet is for you to keep.