

The Australian Breakthrough Cancer Study

Participant Information

This *information* has been written to help you to decide if you would like to take part in the Australian Breakthrough Cancer (ABC) Study.

Please read the *Participant Information* carefully.

If you have any questions, please contact the study team on 1800 688 419 or email info@abcstudy.com.au.

1. Your consent

If you agree to participate in this study, you will be asked to give your consent. This will indicate that you have read and understood this information and that you freely agree to take part in the ABC Study as described.

Please print or save the study information and Consent Form for your records.

2. Who runs The ABC Study?

The ABC Study is run by Cancer Council Victoria. The chief investigators are Professor Graham Giles, Director of Research of the Cancer Epidemiology and Intelligence Division (CEID), Dr Roger Milne, Director of CEID and Dr Fiona Bruinsma, who is the Research Co-ordinator.

The ABC Study has been approved by the Human Research Ethics Committee of Cancer Council Victoria. This study will be carried out according to the National Statement on Ethical Conduct in Human Research (2007).

3. What is The ABC Study about?

The ABC Study will investigate the genetic basis of cancer and other diseases (such as heart disease and diabetes), exploring the ways that our lifestyle and environment can affect genes, and aiming to identify the genetic changes that lead to the development of disease. It aims to look at disease at the level of an individual's genetic makeup and improve our ability to predict the risk of an individual developing cancer. It is hoped that this will lead to more precise methods of screening for the presence of cancer and better targeted cancer prevention strategies and public health messages.

4. Who will be taking part in the study?

Those taking part in the ABC Study are Australian residents from 40 to 74 years of age and have never been diagnosed with cancer, other than non-melanoma skin cancer.

5. What does the study involve?

If you decide to take part in the ABC Study, you will be asked to do the following tasks.

(a) Questionnaires

You will be asked to complete three online questionnaires:

1. *Family History*: asks about your family and the history of cancer in your family. We are asking you to provide details of your family members to determine the number of diagnoses of cancer within your family.

2. *Health and Lifestyle*: asks questions about your body size history, smoking, some health conditions, use of medications, medical tests and your daily activities.
3. *Diet*: asks questions about your eating habits and alcohol consumption.

It is difficult to estimate the time that the questionnaires will take to complete, because it depends on the complexity of your family structure and medical history. You will not have to complete all the sections at one time. Once registered, you will be able to log in and out at any time. All completed details will be saved for you to continue at your convenience.

We will email you a link to complete the questionnaires online. You are welcome to get someone to help you complete the questionnaires, if needed.

You may want to inform your family members that you are participating in the study and are providing us with their details. You should, where possible, let them know and tell them about this information in this Information Sheet.

(b) Biological samples

As we will be studying the role of genes in the development of cancer and other chronic diseases, we need to study your genetic characteristics. To do this, we will be collecting some biological samples so that we can analyse your DNA (the chemicals that make up our genes).

- Saliva sample

You will be required to provide a saliva sample.

A saliva kit will be sent to you in the post, which can then be returned to the study team in the reply-paid envelope we will provide for you.

- Blood sample

Some participants will also be asked to provide a blood sample.

If we need a blood sample from you, we will ask you to visit your nearest pathology collection centre. Providing this sample is not mandatory. You will not incur any costs from providing this sample.

- Tissue samples

The ABC Study will be following the health of participants over a long period of time. Some participants might develop cancer, and part of their diagnosis or treatment may involve the removal of tumour tissue. As samples of these tissues are usually stored by the pathology laboratories, the ABC Study will request access to tissue samples from the laboratories for use in the study.

Any saliva, blood or samples collected from you will be stored indefinitely at The University of Melbourne's Genetic Epidemiology Laboratory. They will be stored securely and only Cancer Council Victoria and Melbourne University authorised staff will have access to them. Your biological samples will be labelled with a unique code and only designated staff will be able to link that code to you.

Your de-identified samples could also be provided to other researchers in the future, for use in studies that have been approved by Cancer Council Victoria's Human Research Ethics Committee.

As this type of research takes many years to conduct, participants agree to their personal information (including sensitive health information) being collected over many years and to alert us of any change to postal or email address, so that we may stay in touch to keep our records accurate and complete.

(c) Future contact

Periodically, we may contact you to invite you to participate in other studies approved by the Human Research Ethics Committee of Cancer Council Victoria. You are not obliged to take part and can opt out of this contact at any time by letting us know. We aim to keep such contact to a minimum.

6. What other information or materials will the ABC Study obtain?

Periodically, information about you may be collected by Cancer Council Victoria from your health records held by health service providers for the purposes of the ABC Study. We also collect information about you from other organisations to update and verify our records without needing to contact you too often. The organisations that we might need to contact include: your doctor; your hospital; Cancer Registries; the Australian Institute of Health and Welfare (AIHW) (National Death Index, Australian Cancer Database), and Electoral Commissions.

Obtaining this information will help us to know about your ongoing health status.

7. How are my privacy and confidentiality protected?

Cancer Council Victoria is subject to privacy and health records laws which regulate how it collects and handles personal information, including sensitive and health information. Further details about how it handles your personal information is set out in its Privacy Policy (as amended from time to time), available on Cancer Council Victoria's website or [here](#). You should review our Privacy Policy regularly, as it may be amended during the course of the ABC Study to reflect changes to our practices and legal obligations.

Information that identifies you, such as your name, date of birth and address will be restricted to staff employed by Cancer Council Victoria to maintain contact with you and the external laboratory that processes your samples.

Written information about you will be stored in an area with access restricted to a small number of staff, who are required to sign confidentiality agreements. All electronic records containing personal information will be stored on a password protected computer system. These will be protected by high level security measures. For further information, please refer to the Cancer Council Victoria Privacy Statement.

De-identified information or samples, that will not include your name or other identifying information, may be made available to other researchers, including interstate and overseas researchers, for studies that have been approved by a Human Research Ethics Committee recognised by Cancer Council Victoria. The purpose of the research would be relevant to the primary purpose of the ABC Study (research into cancer and other diseases). No data obtained from the AIHW would be provided without prior approval of the AIHW HREC.

We will not include your name or other identifying information in any publication.

We have no plans to destroy the information, saliva, blood or other samples we collect because the study will continue indefinitely.

In accordance with applicable Australian and/or Victorian health privacy legislation, you have the right to access certain information about you that is collected and held by us. This will include genetic information that is health or sensitive information about you. You also have the right to ask for certain information to be corrected.

Contact the study team on 1800 688 419 or email abcstudy@cancervic.org.au if you would like to access your information. If you do so, once we verify your identity, you will receive a copy of all submitted questionnaires and responses, as well as any interpretable and applicable clinical findings available at the time of request.

8. How can I find out what the researchers learn from the study?

All participants will occasionally be sent newsletters which will highlight any interesting findings, as they become available, or future plans for the study.

Research can take a long time. We need to collect and test samples from many people before we can draw meaningful conclusions. The research using the information you provide could take some years to complete.

We will not be providing you with the results of genetic analyses, unless we find there are interpretable results that have important implications for your health or the health of your family and you can be reasonably identified. If our research uncovers any such information, we will seek approval from Cancer Council Victoria's Human Research Ethics Committee to contact you, or the members of your family affected by the information, and offer access to this information in

accordance with applicable privacy law. You, or your family members, may decline to receive the information.

Participation in the study should not alter your use of routine health care or health screenings in any way.

9. Are there any benefits to me?

You might not receive any direct benefits by participating in the ABC Study, but the results of the research could benefit others in the future. This study is specifically looking at the influence of genetic and environmental factors on the risk of developing cancer and other chronic diseases. This will allow us to better prevent and treat these diseases in the future, including developing medical and screening programs that are more personalised.

10. Are there any risks to me?

Providing a saliva sample can be thought to be an unpleasant process. For those providing a blood sample, there could be a little discomfort as the needle goes through the skin and there might be some bruising. Feelings of light headedness or fainting might occur, in which case the person taking the blood will assist until the feeling goes away.

11. What if I no longer want to participate?

You can withdraw from the study at any time, without giving a reason, by contacting the study team on 1800 688 419 or email abcstudy@cancervic.org.au. If you choose to withdraw, we will continue to use your information and/or saliva, blood and tissue samples in the research unless you instruct us otherwise. Please let the study team know if you do not want us to continue using your information or samples. If you no longer want your information or samples to be used, they will be de-identified and/or destroyed securely.

12. What if I have more questions?

If you have any questions about the ABC Study, or would like any additional information before deciding to participate, please contact the study team on 1800 688 419 or email info@abcstudy.com.au

13. What can I do if I have a complaint?

Cancer Council Victoria's Human Research Ethics Committee has approved this study based on strict ethical standards and security of participant confidentiality and privacy. If you have any complaints or concerns about the manner in which this research is being conducted or how your personal information is being handled, please contact Ms Cathy Schapper, Executive Officer of the Human Research Ethics Committee, tel: (03) 514 6318, email cathy.schapper@cancervic.org.au or contact the Office of Australian Information Commissioner at enquiries@oaic.gov.au or tel: on 1300 363 992

Thank you for your time. If you have any questions about The ABC Study, or want to talk about taking part in it, please call the study team on 1800 688 419 or email abcstudy@cancervic.org.au .