

## The Australian Breakthrough Cancer Study

### Linkage with MBS/PBS

#### Participant Information

This information has been written to help you to decide if you would be willing to consent to the ABC Study obtaining data on your health and medication use and for the release of your Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) claims information.

#### What is The ABC Study about?

The Australian Breakthrough Cancer (ABC) Study is a long-term study working with over 50,000 Australians to investigate the causes of common non-communicable diseases, particularly cancer. The ABC Study will investigate the role that our genes, lifestyle and environment play in the development of cancer and other diseases.

The aim is to improve our understanding of risk factors for the development of cancer and to examine health after a cancer diagnosis.

#### Your consent

If you agree to us obtaining this data, you will be asked to give your consent to indicate that you have read and understood this information, and that you freely agree to the conditions described in this participant information sheet. Please print or save the Participant Information Sheet and Consent Form for your records.

Services Australia is not involved in the conduct of this study other than to release your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information.

Services Australia will not provide your personal information to the study without your consent. To participate in the study, you must complete the 'Services Australia Participant Consent Form'.

You will be asked to sign a consent form authorising the study to access your complete MBS and/or PBS information as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent of your Services Australia personal information to the Study is completely voluntary and there will be no cost to you. If you do not want to consent to the release of your Services Australia personal information you do not have to. You should feel under no obligation to consent to the Study. Choosing not to participate in the study will not affect your current and future medical care in any way.

#### Who runs The ABC Study?

Obtaining health and medication use data from the MBS/PBS is a part of the ABC Study which you are already participating in being undertaken by Cancer Council Victoria. The chief investigator is Professor Roger Milne, Head, Cancer Epidemiology Division (CED). Principal investigators are Professor Graham Giles, Distinguished Research Fellow, CED; Dr Fiona Bruinsma, CED Senior Manager, Associate Professor Brigid Lynch, Deputy Head, CED, and Professor Melissa Southey, Precision Medicine, Monash University.

### Does the study have approval from an ethics committee?

The 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, updated 2018) (HREC No 1403).

Services Australia has confirmed that a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC), and operates within guidelines set out by the NHMRC has approved this research and any associated documents.

### Do I have to participate in this component of the study?

Your participation in this component of the study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

### What if I no longer want to participate?

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw from the study at any time by completing and signing the '[Participant Withdrawal of Consent Form](#)' or by contacting the study team on 1800 688 419 or email [abcstudy@cancervic.org.au](mailto:abcstudy@cancervic.org.au). This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you. If you no longer want your information they will be de-identified and/or destroyed securely. If you withdraw after analyses have been undertaken, it may not be possible to withdraw all data as it may have been included in analyses.

You are under no obligation to continue with the consented release of your Services Australia information. You may change your mind at any time about releasing your information to the Study.

You can withdraw your consent to release your Services Australia information by completing and signing the 'Services Australia Participant Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw your consent at a later date.

### What does the study involve?

The ABC Study is a long-term study that aims to investigate the development of cancer and other diseases across many years.

For this component of the study we are asking for consent to:

- i. link with records held by the Pharmaceutical Benefits Scheme (PBS) to investigate the risk of cancer and other diseases associated with use of analgesics, medications for acid-related disorders (for example antacids and proton pump inhibitors) and medications that act on the cardiovascular system (for example antihypertensive medications, statins, ACE inhibitors)
- ii. link with records held by the Medicare Benefits Schedule (MBS) on diagnostic procedures and investigations, imaging services, pathology services and therapeutic procedures following a diagnosis of cancer. This will enable us to obtain a comprehensive picture of health following a diagnosis of cancer.

The information obtained will be stored with identifiers removed and will only be available for use by the ABC Study team. This information will be retained for at least 15 years. At the end of this time either a request will be made to retain this data for an additional period or the electronic data will be destroyed (including archive versions but excluding where data has been incorporated into analysis files used for publication of findings).

Your personal information specified within the consent form will be sent securely to Services Australia to authorise the release of your Services Australia information to the Study. Services Australia will retain your consent form for the life of the study as a record of your consent. A copy of your consent form will also be retained by the ABC Study for the life of the study. Your Services Australia information will be de-identified and stored securely by the ABC Study on servers, or hosted through cloud computing providers, physically located within Australian borders. Your Services Australia information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

Your Services Australia information that has been included in de-identified databases will be securely destroyed after the final publication of the study. However, if you withdraw from the Study you can request the destruction of your Services Australia information, provided it has not been deidentified, analysed and published. All information will be securely destroyed at the completion of the study in a manner appropriate to the security classification of the record content.

## 7. How are my privacy and confidentiality protected?

All electronic records containing personal information held by the Cancer Epidemiology Division (CED), CCV are accessed via password protected computers at CCV. Data are stored in compliance with the Commonwealth Privacy Act. Further details about Cancer Council's Privacy Policy are available on the website <https://www.abcstudy.com.au/home/siteinfo/privacy>.

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.

Access to 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 for the duration of your participation in this study.

Electronic data relating to this project are stored securely within private cloud computing environments. CCV has agreements with each hosting company which conforms to, and is compliant with, CCV's privacy policy and are certified as compliant. The hosting company vendor provides and manages the physical servers located within their data centre. The virtualised servers are contained within data centres based in south-eastern Australia and there is no cross-border transmission of data outside of Australia. A secure link is used to access data at the data centre from the CCV network. Only authorised staff using PCs within the CCV's secured IT network are able to access data hosted on the cloud computing services. These staff are required to sign confidentiality agreements as a condition of their employment. For further information, please refer to the Cancer Council Victoria Privacy Statement.

Government agencies and publishers of scientific journals sometimes require research data to be available via open or mediated access data repositories that meet international security and safety standards for sharing data. In such cases, no individually identifiable data would be provided. We will not include your name or other identifying information in any publication.

In accordance with relevant Australian and/or Victorian privacy legislation, you have the right to access the information about you that is collected and held by us. You also have the right to ask for information to be corrected. Contact the study team on 1800 688 419 or email [abcstudy@cancervic.org.au](mailto: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 data obtained at the time of request.

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

#### 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 will examine the association between medication use and risk of cancer and other diseases as well as looking at the health of individuals post a cancer diagnosis. This will allow us to better prevent and treat these diseases in the future.

#### Are there any risks to me?

The risk to you is low. We are collecting information on your medication and health service usage. Once the data is obtained it will only be analysed with identifiers removed.

#### Sources of funding

The Australian Breakthrough Cancer (ABC) Study is funded by Cancer Council Victoria and a generous gift from the Geary Estate.

#### 14. 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](mailto:info@abcstudy.com.au)

#### What can I do if I have a complaint?

Cancer Council Victoria's Human Research Ethics Committee (HREC No.1403) 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, please contact the Research Program Governance Unit of the Cancer Council Victoria via [RGU@cancervic.org.au](mailto:RGU@cancervic.org.au) or contact the Office of the Australian Information Commissioner at [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au) or tel: 1300 363 992

If you have a privacy complaint in relation to the use of your Services Australia information, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: [www.oaic.gov.au](http://www.oaic.gov.au)  
Telephone: 1300 363 992  
Email: [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au)  
Mail: GPO Box 5218, Sydney NSW 2001

Your personal information Services Australia hold is protected by the Privacy Act 1988 and cannot be given to a third party without your consent or where otherwise permitted by law. For more information about privacy, go to [servicesaustralia.gov.au/privacy](http://servicesaustralia.gov.au/privacy)

Thank you for your time.