

The Australian Breakthrough Cancer Study: Faecal (poo) sampling

Participant Information

This information has been written to help you to decide if you would be willing to provide a faecal (poo) sample as part of the Australian Breakthrough Cancer (ABC) Study.

Please read this information carefully.

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

1. Your consent

If you agree to provide a sample, 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. This includes consenting to the completion of questionnaires and collection and analysis of your poo sample by Cancer Council Victoria.

Please print or save the Participant Information Sheet and Consent Form for your records.

2. Who runs The ABC Study?

Faecal sample collection is a part of the ABC Study 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, Senior Manager, Research Coordination, CED; Associate Professor Brigid Lynch, Deputy Head, CED and Professor Melissa Southey, Precision Medicine, Monash University.

3. Does the study have approval from an ethics committee?

Faecal collection 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).

4. Why am I being asked to provide a faecal (poo) sample?

The sample will provide information about your microbiome. The microbiome is the community of microorganisms living on and inside you, including in your gut, mouth, and on your skin.

Recent estimates suggest there are more microbial cells in your body than human cells. These microorganisms play an important role in our health.

We hope to obtain a poo sample from all ABC Study participants to further complement the depth of information contained in the study and available for future research.

5. Why is the gut microbiome important?

Particular research interest is focussed on the gut microbiome, its role in priming the human immune system, and its potential to influence many aspects of health, including risk of cancer.

6. What does participating in this part of the study involve?

If you agree to take part, you will be asked to do the following tasks:

Biological sample

We will be collecting a poo sample in order to analyse the DNA of your gut microbiome.

You will be sent a kit to collect the poo sample using collection cards and a tube containing 2.5ml of 95% ethanol.

The kit will be sent to you in the post, which you should then return with your sample in the reply-paid envelope to the Precision Medicine Biorepository (PMB) at Monash University, where your sample will be stored and analysed. You will not incur any costs from providing these samples.

Log on to the ABC Study website and complete an online questionnaire

- *Day of sampling* questionnaire asks about your health and activity on the day you provide the sample
- *Diet* questionnaire asks about the food you eat and what you drink.

It is difficult to estimate the time that the questionnaires will take to complete; however, it is likely that they will take between 15-30 minutes. You do not have to complete all the sections at one time: you are able to log in and out at any time, and all the details you fill in are saved for you to continue at your convenience.

Some of these questions are similar to those you were asked to complete for the ABC Study; we ask that you complete them again, as we require this information to be current at the time you provide the poo sample.

You are welcome to get someone to help you complete the questionnaires, if needed.

7. What will be done with the samples and data I provide?

Once your samples have been received, they will be frozen and stored indefinitely at the Precision Medicine Biorepository (PMB) at Monash University.

The samples will be stored securely and only authorised staff at Cancer Council Victoria and Monash University (PMB) will have access to them. Your samples will be labelled with a unique code, your initials and date of birth and only designated staff will be able to link that code to you.

Questionnaires and any microbiome data generated will also be stored separately from identifying information we hold on you.

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 are set out in its Privacy Policy (as amended from time to time), available on [Cancer Council Victoria's website](#). 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. 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. Access is restricted to a small number of staff who are required to sign confidentiality agreements.

Your information or samples, which 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 any such research would be relevant to the primary purpose of the ABC Study (research into cancer and other diseases). 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.

Cancer Council Victoria has no plans to destroy the information or samples we collect because the study will continue indefinitely.

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 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?

Samples are collected and stored for research purposes and will not be analysed immediately.

We will not be providing you with the results of microbiome 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 may not receive any direct benefits by providing a poo sample to the ABC, but the results of the research could benefit others in the future. The aim of collecting gut microbiome samples from ABC participants is to investigate the relationship between the gut microbiome and the development of 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?

You will be asked a range of questions about your health and lifestyle that some people may find intrusive. You are only required to answer the questions that you feel comfortable in answering. Providing a poo sample might be considered an unpleasant process. You have the option of opting out of this part of study. Ethanol is considered a flammable liquid; however, due to the small volume provided in the study the risk to participants is low. The sample kit contains a detailed instruction sheet that will explain how to provide the sample cleanly and safely. If you have any concerns, contact the study team on 1800 688 419.

11. What if I no longer want to participate?

You can withdraw from providing a poo sample or the ABC 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 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. If you withdraw after analyses have been undertaken, it may not be possible to withdraw all data as it may have been accessed and used for other ethically approved studies.

12. Sources of funding

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

Funding to collect poo samples is provided by Gandel Philanthropy and Perpetual Trustees.

13. 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

14. 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 or contact the Office of the Australian Information Commissioner at enquiries@oaic.gov.au or tel: 1300 363 992

Thank you for your time.