

The ABC Accelerometer Sub-Study

Participant Information

Please read the participant information carefully.

This information will help you to decide if you would like to continue to take part in the ABC Accelerometer Sub-Study, which is an additional component of Australian Breakthrough Cancer (ABC) Study.

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 at the end of this document. Please sign and return the consent form with both the devices and diary. The consent form will indicate that you have read and understood this information and that you freely agree to take part in the ABC Accelerometer Sub-Study as described.

It is recommended that you copy, print or save the ***Participant Information*** and ***Consent Form*** for your own records.

2. Who runs the ABC Study and ABC Accelerometer Sub-Study?

The ABC Study is run by Cancer Council Victoria. The Chief investigators are Professor Graham Giles, Associate Director of the Cancer Epidemiology Division & Head of Research, Associate Professor Roger Milne, Director of the Cancer Epidemiology Division, and Dr Fiona Bruinsma, who is the Research Co-ordinator.

The researchers overseeing the ABC Accelerometer Study are Associate Professor Brigid Lynch, Senior Research Fellow, and Dr Nga Nguyen, Postdoctoral Fellow, Cancer Epidemiology Centre, Cancer Council Victoria.

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

3. What is the ABC Accelerometer Sub-Study?

Physical activity and prolonged sitting are important lifestyle behaviours which should be explored for their possible links with disease occurrence in population and for seeking opportunities to improve health status of the communities. This study aims to collect data on how much time individuals spend in different types of reclining, sitting and moving activities. This information will

allow our scientists to examine how different patterns of sitting or moving are related to various health outcomes, including processes that lead to cancer, cardiovascular diseases and type II diabetes (e.g., body composition, or biomarkers such as blood glucose levels).

4. Who will be taking part in the ABC Accelerometer Sub-Study?

Participants of the Australian Breakthrough Cancer Study (ABC) Study (who are Australian residents, aged 40 to 74 years at registration, and have never been diagnosed with cancer) who have agreed to provide a blood sample as part of the ABC Study will be eligible to be randomly selected to take part in the ABC Accelerometer Sub-Study.

5. What does this sub-study involve?

If you decide to take part in the ABC Accelerometer Sub-Study, you will be asked to do the following:

Wear an accelerometer and inclinometer for seven (7) days.

You will be asked to wear an accelerometer, which is similar to a pedometer, for seven (7) days. This device is about the size of a box of matches, and worn on an elasticised waistband (under or over clothes). The accelerometer will be worn during waking hours only (not during your sleep time).

You will also wear an inclinometer at the same time, for seven (7) consecutive days. This device looks a bit like a domino, and it is worn on the right thigh and adhered to the skin with a hypoallergenic adhesive patch. The inclinometer will be worn all the time (24 hours per day for seven (7) consecutive days).

If you agree to take part in this sub-study, we will provide you with a package that will contain:

1. One Actigraph GT3X plus accelerometer device (with elasticised waist band);
2. One activPAL inclinometer device (plus three hypoallergenic adhesive patches and a SKIN-PREP protective wipe);
3. Separate instructions with illustrations demonstrating how to wear these devices;
4. A diary, so that you can tell us when you put the accelerometers on (and took it off) each day;
5. A **consent form to be signed and returned with the pack;** and
6. A postage-paid satchel for you to return these materials to us after wearing the devices for seven days.

6. What other information or materials will the study obtain?

We shall not obtain any information about you other than has been outlined in this information sheet.

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. Information that identifies you, such as your name, date of birth, and address will be restricted to staff employed by Cancer Council Victoria.

Written information about you will be stored in an area with access restricted to a small number of staff all of whom 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 available on Cancer Council Victoria's website.

Your information, that will not include your name, may be made available to other researchers, including interstate and overseas researchers, for studies that have been approved by Cancer Council Victoria's Human Research Ethics Committee.

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

In accordance with relevant Australian and/or Victorian privacy and other legislation, you have the right to access the information about you that has been 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 be sent a brief report that summarises your activity data collected by the accelerometer and inclinometer. We can also provide you with questionnaire responses, and 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 as part of the broader ABC Study. We may include some interesting findings from the ABC Accelerometer Sub-Study in future newsletters. Individual participants will not be identified in any articles; only aggregate response data will be discussed.

Research can take a long time. We need to collect consult many people in this process 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 personal results. 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 Accelerometer Sub-study, but the results of the research could benefit others in the future. This study is specifically designed to compare self-reported with objectively determined physical activity and sitting behaviour in order to improve accuracy and precision in cancer risk estimations. Your participation will allow us to better understand health and disease dynamics.

10. Are there any risks to me?

Adhering the activPAL accelerometer to the thigh may irritate the skin. If skin irritation is uncomfortable or distressing, discontinue use of the device immediately and consult your doctor. Please also contact the ABC Study team. You will be provided a SKIN-PREP protective wipe designed to protect your skin and reduce the risk of irritation.

The waist monitor, although small can also be uncomfortable for some. The waistband may rub and irritate skin if worn under clothing. It is recommended that you wear the waistband over clothes if socially appropriate and again cease use if too uncomfortable.

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 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.

12. What if I have more questions?

If you have any questions about ABC Accelerometer Sub-study, or would like any additional information before deciding to participate, please contact the study team on 1800 688 419 or email abcstudy@cancervic.org.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, please contact Ms Cathy Schapper, Executive Officer of the Human Research Ethics Committee, telephone: (03) 9514 6318, email cathy.schapper@cancervic.org.au. Or contact the Office of Australian Information Commissioner at enquiries@oaic.gov.au or telephone on 1300 363 992.

Thank you for your time. If you have any questions about The ABC Accelerometer Sub-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.

The ABC Accelerometer Sub-Study

Consent Form

(Please sign this form and send back with devices in postage paid envelope)

I consent to take part in the ABC Accelerometer Sub-Study

I freely agree to participate in the **ABC Accelerometer Sub-Study** according to the conditions in the Participant Information.

I have read, or have had read to me, and understand the Participant Information and Cancer Council's privacy Policy.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

The Participant Information document and this Consent Agreement are available for me to copy.

I understand that the study team will not reveal my identity and personal details in any information about the **ABC Accelerometer Sub-Study** that is published or presented in any medium.

I understand that I can withdraw my consent to take part in the **ABC Accelerometer Sub-Study** at any time.

I give consent for my de-identified information to be provided to researchers for use in other ethically approved research projects outside the **ABC Accelerometer Sub-Study**.

I understand I will not receive any direct benefit from taking part in the **ABC Accelerometer Sub-Study**.

Participant Name: _____

Participant: _____
(Signature)

Date: _____