



**BC Cancer Agency**

CARE & RESEARCH

An agency of the Provincial Health Services Authority



**BC GENERATIONS PROJECT**  
Your time today builds a healthier tomorrow.

RESEARCH CENTRE

## Participant Information and Consent Form BC Generations Project

We would like to invite you to participate in the BC Generations Project. The BC Generations Project is collecting data and biospecimens from up to 40,000 British Columbians between 35 and 69 years old. This collection will form the basis of thousands of studies over the next few decades that seek to understand how to prevent cancer and other chronic diseases. This research project is part of a Canada-wide initiative sponsored by the Canadian Partnership Against Cancer known as the Canadian Partnership for Tomorrow Project. This is the largest health initiative of its kind and includes the BC Generations Project, the Alberta Tomorrow Project, the Ontario Health Study, Quebec's CARTaGENE, and Atlantic PATH (Nova Scotia, New Brunswick, PEI, Newfoundland and Labrador).

We ask you to read this information pamphlet in order to decide if you would like to participate in this research. We would like to explain why the BC Generations Project has been set up, its aims and purposes, and what your participation will involve. Please take the time to read the following information carefully. Ask us if there is anything that is not clear, or if you would like more information. **Participation is voluntary**, and if you do not wish to participate, it will not affect your medical care in any way.

### Contact Details:

If you have questions, please call 604-675-8221 or toll-free at 1-877-675-8221.

You may also contact us by mail or email:

BC Generations Project  
675 West 10<sup>th</sup> Avenue  
Vancouver, BC V5Z 1L3  
[bcgenerationsproject@bccrc.ca](mailto:bcgenerationsproject@bccrc.ca)

More information is available at [www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca)

**BC Generations Project Co-Principal Investigators:** Dr. Nhu Le (604) 675-8052

Dr. Trevor Dummer (604) 827-2708

## Background

We plan to enrol 300,000 Canadians across Canada. Five regions (British Columbia, Alberta, Ontario, Quebec and Atlantic Canada) are working together to ensure common procedures and still allow for regional specialties. Canadians like yourself who are 35-69 years of age and from all walks of life are invited to complete a questionnaire detailing environmental and lifestyle information, and either now or at some time in the future, donate a blood and urine sample. We may also ask you now or in the future to have a number of physical measurements taken, including blood pressure, grip strength, and body fat. This will conclude your enrolment in the BC Generations Project. However, we may also want to ask you more questions about past exposure to particular substances, or possibly to ask for new samples in the future. Although our requests for new information and specimens may occur only every few years, the BC Generations Project will continue until 2058 because your information and specimens will become more valuable for medical research as time elapses.

### 1. What are the objectives of the BC Generations Project?

The objective of BC Generations Project and all the regions in the Canadian Partnership for Tomorrow Project is to examine connections of environmental factors, lifestyle, and genetics with the development of cancers and other chronic diseases in order to guide future disease prevention programs.

### 2. Who may participate in the BC Generations Project?

You may choose to participate in this study if:

- You understand what you are being asked to do, and you give your informed consent to participate by signing the consent form.
- You are currently living in **B.C.**
- You are between **35 and 69** years of age.

### 3. What does participation in the BC Generations Project involve?

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

- Allow ongoing access to information on your health and use of health services provided by the Ministry of Health and other disease registries in British Columbia (described in section 3.1);
- Allow us to re-contact you from time-to-time for follow-up research (described in section 3.2);
- Allow storage and access of your samples and health-related information obtained for this study in a coded form which does not identify individuals. This information may be used for health research projects until the year 2058 (described in section 3.3);

- Allow us to link the above information and samples together to study the causes of disease;
- To answer a questionnaire about your health and lifestyle and your family and medical history which will take about 45 minutes;
- Allow us to contact you and ask you to complete additional questionnaires in the future;
- To donate a blood sample of about 3 tablespoons (collected by healthcare professionals), a urine sample and possibly a saliva sample, all of which will be stored for use in future studies. These can be donated in your local area and we will send you information on the location of labs close to you and a sample requisition for you to take to the lab.
- If asked in the future, to have a number of physical measurements taken, including blood pressure, grip strength, and body fat.

### 3.1 Access to your health records

We are asking your permission to access information on your health and health procedures that may occur in the future, or may have occurred in the past, as far back as 1985. The sources of this information include existing electronic data files such as:

**BC Cancer Agency:** The BC Cancer Agency keeps a highly-confidential and accurate registry of all cancer cases diagnosed in British Columbia, and all deaths from cancer in the province as well as information on screening procedures and cancer treatment. Information from you will be linked to the BC Cancer Agency databases. The information that will be accessed includes cancer screening, any diagnosis of cancer, along with the date of that diagnosis, the type of cancer, and treatment received. In addition, information on your vital status will also be obtained from the BC Cancer Agency which receives that information from the Vital Statistics Agency of the BC Ministry of Health.

**Population Data BC:** The BC Ministry of Health keeps confidential records of the health services used by all residents, and these records are the most accurate and complete source of this type of information in British Columbia. A study about the causes of disease needs to include information about chronic diseases developed as well as the types of health care services people need, how often services are used, and whether the services are provided at a doctor's office or in a hospital. This information will be accessed by researchers through Population Data BC, a secure facility at the University of BC which acts as an agent of the Ministry to provide information for research applications. The information that Population Data BC will provide to researchers will contain a unique code to identify your information in the study, but not your personal health number, name or any other identifying information. Besides information provided by you to the BC Generations Project, the information may include whether you have died or moved from British Columbia, physician and other health professional services, prescription drugs dispensed, hospital discharge abstracts home and community health services, and mental health services and other information related to chronic disease. In addition should you pass away during the course of the study, vital statistics information such as cause of death, and conditions contributing to your death may be provided. No medical records, notes, etc. will be requested from your family physician or any other physician you may be referred to.

### **3.2 Re-contact for follow-up research**

We ask for your permission to re-contact you in the future to invite you to participate in follow-up parts of this Project (e.g., providing additional samples or answering additional questionnaires), or in new health research projects. Any future involvement will be entirely optional. We will also ask you for the contact information of a relative or friend in case we lose contact with you. They will only be asked for updated contact information. They will not be told about or asked about your health information, but will be told about your participation in this project in order to explain why we are asking for your new contact information.

### **3.3 Storage of samples and information (while protecting your confidentiality)**

We will ask for your permission to store your samples and information for future use in health research studies. Your information and samples will be collected, coded, and stored at highly secure and protected sites at the Cancer Research Centre of the BC Cancer Agency. Only authorized personnel will have access to them under controlled conditions. Personal identifiers such as your name and address will be removed and replaced by a unique code. It will enable us to link the information from different datasets, but at the same time, the unique code will enable us to keep your identity completely confidential when we allow authorized researchers to use your data. Researchers will only be given access to coded information that cannot be used to identify you or any other participants. Any researcher requesting access to information will also be required to have the project reviewed by a Research Ethics Board, sign a confidentiality agreement, and sign an agreement restricting data use only to the approved project.

## **4. What are the benefits of the BC Generations Project?**

The BC Generations Project will contribute to a better understanding about the causes of cancer and other chronic diseases and the factors that influence health and illness among Canadians. Health benefits from this research are likely to help future generations, but your participation in the BC Generations Project is not expected to provide you with any direct individual benefits or personal health results beyond those offered as part of your physical measurements.

## **5. Are there any risks for me in joining the BC Generations Project?**

There are no major health risks involved in this project. Blood collection performed by a qualified health professional sometimes causes bruising, pain, or rarely, fainting. Disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released is estimated to be extremely small, and every effort will be made to protect your privacy and the confidentiality of these results.

## 6. Who will be able to use my information and samples?

The BC Generations Project expects to receive requests from Canadian and overseas scientists and international collaborators to use the information or your sample (with your identifying information removed). All access will be subject to the strictest scientific and ethical scrutiny and independent oversight. Every health research project that uses data or samples from the BC Generations Project must obtain the approval of a properly constituted Research Ethics Board before that new research is conducted. A Research Ethics Board oversees research projects that involve humans (or information or material collected from humans) for the purpose of research, to ensure that the research proposed will be carried out according to the highest ethical and scientific standards.

Your confidentiality will be respected in compliance with applicable laws and regulations. Your medical and study records will not be publicly available. Your identity will not be used in any reports about the study. Identifying information will be used only to confirm that the correct match is made between information from different sources and biologic specimens, to confirm your consent in the event we re-contact you for more information, or to remove your information and samples from the study if you withdraw. All information will be kept under the most stringent security conditions at the BC Cancer Research Centre in Vancouver and Population Data BC. In the future, a copy of your information, with no personal identifying information attached may also be stored at a central database in Canada under the same strict parameters as noted above. This will vastly simplify dealing with requests for data from scientists for approved projects.

Biological samples (blood, urine and possibly other biological samples) will be maintained by the BC Cancer Agency. In order to ensure uniform and secure storage conditions for the Generations Project samples and increase our ability to meet the needs of scientists for approved research projects, the de-identified samples may be moved to one or more British Columbia or Canadian bio-repositories. However, even if this takes place, the BC Cancer Agency will maintain control of all samples and their use.

Representatives of Health Canada and the University of British Columbia (UBC) / British Columbia Cancer Agency (BCCA) Research Ethics Board may inspect your research records for the purpose of auditing the research only. The Ministry of Health Services may also audit the research data holdings originating from the Ministry to ensure security and to confirm the data are used only for approved purposes. However, no records that identify you will be allowed to leave the centre.

Your rights to privacy are legally protected and guaranteed by provincial laws to insure that your privacy is respected. Further details about these laws are available on the web site of the BC Information and Privacy Commissioner, [www.oipcbc.org](http://www.oipcbc.org).

Please call 604-675-8221 or toll-free at 1-877-675-8221, or visit our website ([www.bcgenerationsproject.ca](http://www.bcgenerationsproject.ca)) for further information about our privacy and security practices.

## 7. What happens to my information and samples in the future?

Information and samples collected by the BC Generations Project will continue to be stored and may continue to be linked to other health databases and used by researchers until 2058 or until you withdraw from the study. If you become unable to make decisions for yourself or die, your data will still remain in the study.

## 8. Will I benefit from any commercialization of the research?

Research using your data and samples might someday lead to the development and sale of a medical or genetic test or product. This may be done by a university or hospital, or a commercial company, because sometimes researchers are funded by or work with companies. This means that researchers, including, potentially, commercial companies, may benefit financially. You will not derive any personal financial advantage from this commercialization. No records from the BC Generations Project will be released for marketing purposes.

## 9. Will I receive any compensation for being involved?

Your participation is on a voluntary basis.

## 10. Can I withdraw from the BC Generations Project?

You are free to withdraw at any time from your participation in the BC Generations Project without giving any reason. There are three types of withdrawal:

- **No further contact:** The BC Generations Project will no longer contact you or ask you to participate in ongoing activities. We will continue to have your permission to keep and use information and samples you have already provided, and to continue to access information in health databases.
- **No further access:** The BC Generations Project will no longer contact you or ask you to participate in ongoing study activities, and will not collect any further information about you from health databases. We will continue to have your permission to keep and use information and samples you have already provided.
- **No further use:** The BC Generations Project will no longer contact you or ask you to participate in ongoing study activities, collect additional information about you, any information you have already provided will be removed from our databases, and all biological samples will be destroyed. It is not possible to remove information or samples that have already been provided to researchers for analyses.

You can withdraw by calling us at 604-675-8221 or toll-free at 1-877-675-8221, by email at [bccrc@bccrc.ca](mailto:bccrc@bccrc.ca), or by writing to the BC Generations Project, 675 West 10<sup>th</sup> Avenue, Vancouver, BC V5Z 1L3. This will be overseen by the Principal Investigator, and you will receive an email or letter to confirm your withdrawal.

## **11. Who will oversee the research?**

The UBC BCCA Research Ethics Board has ongoing independent oversight of the BC Generations Project. The BC Ministry of Health Services will have ongoing oversight of the provision of health services data to the study. The Office of the Information and Privacy Commissioner of BC has reviewed the project and will be updated as it proceeds.

## **12. What if I have concerns about the BC Generations Project?**

The BC Generations Project aims to achieve the highest possible standards at all times. If you have any concerns, or wish to make a complaint about any aspect of the BC Generations Project at any time, you can call us free of charge at 604-675-8221 or toll-free at 1-877-675-8221 (Mon-Fri; 9:00 AM to 5:00 PM) and ask to speak to the Principal Investigator. Alternatively, you can write a letter to: Principal Investigator, BC Generations Project, 675 West 10<sup>th</sup> Avenue, Vancouver, BC V5Z 1L3 or email [bcgenerationsproject@bccrc.ca](mailto:bcgenerationsproject@bccrc.ca).

We take all comments seriously, and we will deal with them as quickly as possible. If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia at (604) 822-8598. If your complaints deal with privacy protection, you may also call the Office of the BC Information and Privacy Commissioner in Victoria at (250) 387-5629. For toll-free access call Enquiry BC at (800) 663-7867 and request a transfer to (250) 387-5629.

**Thank you for considering joining the BC Generations Project.**



**By signing this consent form, I agree to participate in the BC Generations Project and I declare that:**

- I have read and understood the information about the Project. I had the opportunity to ask all the questions I thought necessary. I understand that my participation is voluntary, will not affect my medical care, and I can withdraw from the study at any time.
- I agree to (i) answer a detailed questionnaire regarding my health and lifestyle, (ii) provide a blood and urine sample as described in this consent document, (iii) have basic physical measures taken as described in this consent document.
- I agree to be re-contacted in the future to be invited to complete new questionnaires, provide additional biological samples, or have additional measures taken. I understand that I am free to accept or decline each of these invitations.
- I understand that in the event I am asked to have physical measurements done, the results taken during my assessment will be the only specific results that will be communicated to me.
- I accept that information about me contained in health databases may be made available, in coded form and confidentially, to the BC Generations Project or to approved researchers. This information may go as far back as 1985 and will continue even if I can no longer make decisions or after my death unless I formally withdraw from the study.
- I accept that the data and samples will be destroyed at the end of the project on December 31, 2058 or upon my request should I withdraw.
- I accept that my data and samples may be used by researchers from British Columbia, Canada, and other countries for approved health research projects.
- I accept that my data and samples may be made available for approved projects to collaborating scientists who are associated with commercial enterprises, and I understand that I will receive no personal financial benefit from any possible commercialization of any test or product developed via research on my data or samples.
- I understand that my participation is completely voluntary and that I can withdraw from the project at any time without specific reason by calling 604-675-8221 or toll-free at 1-877-675-8221.
- I understand that I will receive a signed and dated copy of this consent form, including all attachments, for my own records.



**I consent to participate in the BC Generations Project.**

**Participant**

\_\_\_\_\_  
Printed Last name, First name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language:\_\_\_\_\_

Was the subject assisted during the consent process in one of ways listed below?

Yes  No

If yes, please check the relevant box and complete the signature space below:

- The consent form was read to the subject, and the person signing below attests that the BC Generations Project was accurately explained to, and apparently understood by, the subject (**please check if subject is unable to read**).
- The person signing below acted as an interpreter/translator during the consent process (**please check if an interpreter/translator assisted during the consent process**).

\_\_\_\_\_  
Signature of Person Assisting  
in the Consent Discussion

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

**Contact Details:**

For further information, you can:

- Call the BC Generations Project at 604-675-8221 or toll-free at 1-877-675-8221 (Mon-Fri; 9:00 AM to 5:00 PM)
- Write to BC Generations Project, 675 West 10<sup>th</sup> Avenue, Vancouver, BC V5Z 1L3
- Send an e-mail to: [bcbgenerationsproject@bccrc.ca](mailto:bcbgenerationsproject@bccrc.ca)

If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia at (604) 822-8598.

***A signed and dated copy of the present form must be given to the participant.***