



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 will collect data and biospecimens from 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. Funding for community recruitment clinics in British Columbia is provided by the BC Cancer Foundation.

You may have volunteered, or you may have been randomly chosen as someone who is potentially eligible to participate in this study because you are a resident of the province, and not because of any medical condition. We have had no access to any of your health information and are inviting you solely because you live in BC and may be within the ages 35-69.

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 10th Avenue
Vancouver, BC V5Z 1L3
bcbgenerationsproject@bccrc.ca

More information is available at www.bcbgenerationsproject.ca

BCCA Principal Investigator:	John Spinelli	(604) 675-8055
BC Generations Project Director:	Marilyn Borugian	(604) 675-8058

Background

We plan to enrol up to 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 will be 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 such as blood pressure, body fat, lung function and grip strength. This will conclude your enrolment in the BC Generations Project. However, as new scientific information on disease risk factors and prevention becomes available we would like to be able to re-contact you, to keep you informed of how the Generations Project is progressing and inform you of any new scientific findings. We may also want to ask you more questions about past exposure to particular substances, or possibly to ask for new samples. Although our requests for new information and specimens may occur only every few years, the BC Generations Project will continue for at least 25 years 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 BC Generations Project is designed to accomplish 2 major objectives:

- **To enrol up to 40,000 British Columbia residents** into a cohort for research purposes only. A cohort is simply a group of persons usually of roughly similar age who are followed over a period of time. The aim will be to follow participants over the next 25 years as some develop diseases such as cancer or heart disease while others do not. The BC Generations Project will gather information about participant's environmental, occupational, infectious or lifestyle exposures to examine whether these have a relationship to health or disease. The intent of the BC Generations Project is to gather as much information from subjects as possible, because many of the causes of cancer are not yet known. As the purpose of the cohort is to find information about causes of disease rather than treatments no health benefit is expected for participants. However information gathered from the BC Generations Project will be critical to guide future disease prevention programs.
- **To partner with the other provinces in the “Canadian Partnership for Tomorrow” Project**, a cross-Canada cohort which will provide the large numbers needed (up to 300,000 Canadians) to examine connections of environmental factors, lifestyle, and genetics with the development of cancers and other chronic diseases.

2. How was I selected for invitation to the BC Generations Project?

You may have volunteered. However, if you received a letter from us, you were randomly identified as being potentially eligible through the use of commercial directories which collect information for marketing from a variety of sources. These directories comply with all the Canadian consumer privacy regulations, including the federal Personal Information Protection and Electronic Document Act (PIPEDA), and the BC Freedom of Information and Protection of Privacy Act. The only information used to contact you was your name and address. We do not know anything about you and we have not seen your medical records. You may also have heard about the BC Generations Project through media or word of mouth from a friend or relative. We would like you to participate in this study regardless of how you heard about us, and whether you are in good health or have health problems or disabilities.

3. 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.

4. 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 use of health services provided by the Ministry of Health Services (described in section 4.1);
- Allow us to re-contact you from time-to-time for follow-up research (described in section 4.2);
- Allow storage 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 4.3).
- 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;
- 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 lab requisition for you to take to the lab.

Some participants may also be asked now or in the future to allow BC Generations Project staff to measure some or all of: your body composition, blood pressure, grip strength, bone density, and lung function.

4.1 Access to your health records

We will ask your permission to access summary information on health procedures you may undergo in the future, or may have undergone in the past, as far back as 1985. The sources of this information include existing electronic data files such as:

The BC Cancer Registry keeps a highly-confidential and accurate registry of all cancer cases diagnosed in British Columbia and all deaths from cancer in the province. An important aspect of the BC Generations Project is to keep track of the number of people in the study who develop cancer. In order to do this accurately, the Cancer Registry will be checked from time to time to see if any of the people in the study are listed. The information to be obtained from the Registry will be any diagnosis of cancer, along with the date of that diagnosis, the type of cancer, and treatment received.

The BC Ministry of Health Services 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 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. We will ask the BC Ministry of Health Services to confidentially send us information describing the health services used by BC Generations Project participants during the years they continue in the study. The Ministry may provide this information 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 the BC Ministry of Health Services provides to the study will contain an individual code to identify your information in the study, but not your personal health number or name. The information would include physician and other health professional services, prescription drugs dispensed, hospital discharge abstracts containing information on diagnoses and treatments received, home and community health services, and mental health services. 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 would be requested. No medical records, notes, etc. will be requested from your family physician or any other physician you may be referred to.

4.2 Re-contact for follow-up research

We will ask for your permission to re-contact you in the future to invite you to participate in follow-up parts of this BC Generations Project research (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.

4.3 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. When information and samples are collected from you, or from other databases or sources, 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.

5. What are the benefits of the BC Generations Project?

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 at your initial visit.

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.

6. Are there any risks for me in joining the BC Generations Project?

There are no major health risks involved in this project. The main inconvenience is the time to complete the questionnaire. In addition;

- Blood collection performed by a qualified health professional sometimes causes bruising, pain, or rarely, fainting;
- If you are invited to a temporary assessment centre to provide physical measurements after completion of the questionnaire and specimen donation we will assess height and weight, blood pressure, grip strength, lung function and bone density. For the breathing test (lung function), you will be asked to take a deep breath and then blow into a device that uses a small tube to record air flow. This process can sometimes cause dizziness. This part of the personal measurements is not recommended to participants who are suffering from a cold, flu or bronchitis; we will ask about this at the time of your assessment centre visit.

The other measures taken during the appointment are without physical risk. For example, the bone density test will be done by passing ultrasound through your heel, which has bone similar to your hip and spine. This test determines the general strength of your bones. This test only requires putting your bare foot with some alcohol on the

heel, into the ultrasonometer. If you are pregnant or have a pacemaker, you will not participate in the body composition measure. Trained staff will be on site if you wish to express any concerns.

Your questionnaire responses will be entered into the computer by trained staff who have taken a pledge of confidentiality. The answers to questions will not be stored together with any of your personal identifying information. Also, you are free to choose not to answer any question you are uncomfortable with.

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. Security issues will be under constant review by the external Chief Privacy Advisor (Dr. David Flaherty, former BC Information and Privacy Commissioner) to keep our practises up to world-class standards.

7. 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. We are currently in contact with another BC health research facility at the University of BC called Population Data BC which has recently been commissioned to construct the most secure data protection facility possible for health research information. If this facility incorporates even more security provisions than the Cancer Research Centre we will then consider moving de-identified information to that facility. In the future, the Canadian Partnership for Tomorrow (the umbrella organization for all the provincial cohorts) is likely to become a registered non-profit organization to which scientists will apply to obtain access to data for bona fide research projects. In this event, a copy of your information, with no personal identifying information attached may also be stored at their central database under the same strict parameters as noted above. This will vastly simplify dealing with requests for data from scientists from all over Canada for approved projects. Biological samples (blood, urine

and possibly saliva) will be maintained by the BC Cancer Agency. The work and cost of storing the BC samples will become a significant concern as the years pass. In order to minimize costs, ensure uniform storage conditions for samples from all 300,000 Canadians and increase our ability to meet the needs of scientists for approved research projects, the samples may be moved to one or more central 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.

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

8. What happens to my information after the Assessment Centre visit?

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.

9. 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.

10. Will I receive any compensation for being involved?

Your participation is on a voluntary basis.

11. What should I do if I want to take part in the BC Generations Project?

The first step is to contact us. You can do this by telephone: 604-675-8221 or toll-free at 1-877-675-8221; (Mon-Fri; 8:00 AM to 5:00 PM) or by email at bcgenerationsproject@bccrc.ca.

12. What should I do if I do NOT want to take part in the BC Generations Project?

If you are certain that you do not want to take part, you do not have to do anything, however we would appreciate it if you would let us know by telephone at 604-675-8221 or toll-free at 1-877-675-8221 (Mon-Fri 8:00 AM to 5:00 PM), or by email at bcgenerationsproject@bccrc.ca. We may ask you for some information about you so as to understand the group characteristics of those who choose not to take part.

13. What if I am not sure whether I want to take part in the BC Generations Project?

We encourage you to ask for more information by phoning us at 604-675-8221 or toll-free at 1-877-675-8221 (Mon-Fri; 8:00 AM to 5:00 PM). You can also find more information on our website at www.bcgenerationsproject.ca.

14. If I join now, 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 two types of withdrawal:

- The first would not allow further contact with you or further access to your health information. Please note that any information collected from you or from government health databases and any tests already done on your samples up to the point of withdrawal will still be used.
- The second would be withdrawal of your data and samples stored by the BC Generations Project and these data and samples would be destroyed.

You can withdraw by calling us at 604-675-8221 or toll-free at 1-877-675-8221, by email at bcgenerationsproject@bccrc.ca, or by writing to the BC Generations Project, 675 West 10th Avenue, Vancouver, BC V5Z 1L3. This will be overseen by Dr. John Spinelli, and you will receive a letter to confirm your withdrawal.

15. Who will oversee the research?

The BC Generations Project and all research using the data and samples are governed by the Governance Council of the Canadian Partnership Against Cancer. This independent body oversees the study on an ongoing basis. The UBC BCCA Research Ethics Board also 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.

16. 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; 8:00 AM to 5:00 PM) and ask to speak to John Spinelli. Alternatively, you can write a letter to Dr. John Spinelli, Principal Investigator, BC Generations Project, 675 West 10th Avenue, Vancouver, BC V5Z 1L3 or email 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.



Thank you for taking the time to read the information brochure and for asking all the questions you may have about the 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 brochure. I had the opportunity to ask all the questions I had and received satisfactory answers. I was given sufficient time to make an informed decision regarding my participation.
- I agree to (i) answer a detailed questionnaire regarding my health and lifestyle, (ii) provide a blood, urine and possibly saliva sample as described in this consent document, and in the event I am asked, and (iii) have basic clinical measures taken as described in this consent document which include height, weight, body fat, waist and hip circumference, blood pressure, grip strength, bone density, and lung function.
- I agree that the results of any laboratory analyses conducted on my samples in the future for research purposes will be transmitted, in coded form, to the BC Generations Project.
- I agree to be re-contacted by the BC Generations Project in the future to be invited to complete new questionnaires, clinical tests, or measures related to its research work. 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 government health services databases and necessary to this study will be made available, in coded form and confidentially, to the BC Generations Project for use by 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 stored by the BC Generations Project will be destroyed at the end of the project on December 31, 2058 or upon my request should I withdraw. The project Governance Council and the Research Ethics Board may also direct that data and samples be destroyed before 2058.
- I accept that my data and samples, once coded, may be used by researchers from British Columbia, Canada, and other countries for health research projects that have received the necessary approvals.

- 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 the data and samples from the BC Generations Project.
- 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 may ask questions about the BC Generations Project now and in the future.
- 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 for the subject, 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; 8:00 AM to 5:00 PM)
- Write to BC Generations Project, 675 West 10th Avenue, Vancouver, BC V5Z 1L3
- Send an e-mail to: bcgenerationsproject@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.