

CONSENT TO TAKE PART IN A RESEARCH STUDY
Participant Information

STUDY TITLE: Atlantic Partnership for Tomorrow's Health (PATH) Study

**PRINCIPAL
OR QUALIFIED
INVESTIGATOR:** Dr. Louise Parker
Population Cancer Research Program
Faculty of Computer Science
Room 455, 6050 University Avenue
Halifax, Nova Scotia B3H 1W5
Telephone: (902) 494-7284

**ASSOCIATE
INVESTIGATORS:** Please see the study leaflet-for a list of the investigators for this study.

STUDY SPONSOR: CPAC – Canadian Partnership Against Cancer

PART A.

RESEARCH STUDIES – GENERAL INFORMATION

1. INTRODUCTION

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you don't understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

Participation in this study is not expected to provide you with any direct individual benefits other than a report of your physical measures offered at your initial visit.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

PART B.

EXPLAINING THIS STUDY

2. WHY IS THIS STUDY BEING DONE?

The Atlantic Partnership for Tomorrow's Health (PATH) project aims to study how the health of 30,000 people, currently aged 35-69, from Atlantic Canada is affected by their lifestyle, environment and genes. The primary purpose of this major project is to improve the prevention, diagnosis and treatment of cancer, and to promote health throughout society.

Over the coming years, the health of the people in the study will change. For example, some people may develop certain diseases, like cancer, and others will not. We will be able to make comparisons between people based on these changes in health. For example, we will be able to compare those who develop cancer with those who do not, with respect to their health, illness, diet, activity and inherited genetic make-up.

The most important health benefits from the PATH study will be realized many years from now, and will largely help future generations. It will contribute to a better understanding of the causes of disease, and the factors that influence health and illness among a large group of Canadians.

3. WHY AM I BEING ASKED TO JOIN THE STUDY?

You are being asked to join the study either because you were identified by the Nova Scotia Department of Health as being between the ages of 35 and 69, or because you contacted us and expressed an interest in the study. To be eligible for the PATH study you must also be a resident of Nova Scotia, New Brunswick, Prince Edward Island or Newfoundland and Labrador.

It is important that all types of people join the PATH study. We would like you to take part whether you are in good health or have health problems or disabilities.

4. HOW LONG WILL I BE IN THE STUDY?

The initial visit to the assessment centre will take approximately 90 minutes of your time, and involves only one (1) study visit. You may be contacted in the future to provide additional information, attend another assessment centre visit or provide more biological samples (blood, urine, saliva and toenail clippings). However this would be entirely optional.

5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study is part of a national study called, The Canadian Partnership for Tomorrow Project. It is taking place across Canada. The total number of participants in the national study will be three hundred thousand (300,000). We expect that approximately thirty thousand (30,000) participants from Atlantic Canada will take part in this study.

6. HOW IS THE STUDY BEING DONE?

As with all provinces that are part of The Canadian Partnership for Tomorrow Project, the PATH study will collect information on lifestyle and the environment through questionnaires, physical measures and biological samples. Participants will be followed for 30 years, allowing-researchers to study changes in people's health, for example, comparing people who develop cancer with those who do not.

7. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

You will be invited to attend an assessment centre in an area close to where you live. A short pre-visit questionnaire will be included so that you can make a note about certain things that you might not otherwise remember. The appointment at the assessment centre should take about 90 minutes. Participation in this study involves:

- Having a chance to ask any questions that you might have before deciding whether to join
- Answering questions on your health, lifestyle, education, residential history, work and family history
- Having measurements taken of your blood pressure, pulse rate, height (sitting and standing), weight, hip and waist circumference, body fat, grip strength, and heel ultrasound
- Giving a small sample of blood (about 2 tablespoons), urine, and saliva for long-term storage and future analysis (including genetic data). We will also collect toenail clippings to look at long term exposure to potentially toxic substances such as arsenic.
- Receiving information about the results of your physical measurements (see above). This information will be provided with appropriate explanations, showing your measurement alongside "standard measures". If you are concerned about the results of your physical measures, we will advise you to consult your doctor or a qualified medical professional. You can choose not to receive this information if you wish. This visit is not intended to be a "health check". None of your individual results will be released to your doctor.

Note: If for any reason, you might not be able to undergo some of the physical measurements described above you can still participate in other parts of the study.

If you agree to participate, you will also be allowing us permission to access routinely collected information on health procedures you may undergo or may have undergone in the past. The sources of this information include existing electronic data files such as:

Cancer Care Nova Scotia is responsible for keeping a highly confidential and accurate registry of all cancer cases diagnosed in Nova Scotia. This information is used to estimate the rates of new and existing cancer in the population and death rates from various types of cancer. An important aspect of the PATH Study is to keep track of the number of people in the study whether they develop cancer or

not. In order to do this with the most accuracy, the Cancer Registry will be checked from time to time to see if any of the people in the PATH study are listed. The PATH study will also be accessing Vital Statistics records related to death records.

The Nova Scotia Department of Health keeps confidential records of the health services used by all residents, and these records are the most complete source of this type of information in Nova Scotia. 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.

8. ARE THERE RISKS TO THE STUDY?

There are risks with this, or any study. To give you the most complete information available, we have listed some *possible* risks. We want to make sure that if you decide to join the study, you have had a chance to think about the risks carefully. Please be aware that there may be risks that we don't yet know about.

QUESTIONNAIRES

You may find some of the questions that you are asked make you uncomfortable or may upset you. You are not required to answer these questions.

HEEL ULTRASOUND

The heel ultrasound test is not recommended for participants with open sores or lesions on their feet.

BODY FAT MEASURE

This measurement will not be done if you are pregnant or have a pacemaker.

BLOOD, URINE, SALIVA SAMPLES

Blood -You may experience some temporary discomfort when the blood sample is taken. There is a small risk of bruising, infection or swelling at the site where the needle is inserted, and some people may feel faint and dizzy.

Blood, urine, saliva and toenail samples - The kind of information we will look for in the study will not tell you anything specific about your personal health.

To protect your information, we will not keep your name or other information that may identify you with the samples; only a code number. Files that link your name to the code number will be kept separately from any of the measurements, samples or other information about you. Although no one can absolutely guarantee confidentiality, using a code number makes the chance much smaller that someone other than research staff or other authorized groups or persons (discussed later in the consent form) will ever be able to link your name to your sample or to any test results.

Although your name will not be kept with the sample, information provided with your sample may have other facts about you such as your race, ethnicity, and sex. These facts are important because they will help us learn whether or not the factors that cause certain diseases are the same or different in men and women, and in people of different racial or ethnic backgrounds. Thus it is possible that research findings could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with such a group. We do not know the effects that this knowledge could have on you or people like you.

Before you decide whether or not to participate in the PATH study and give us your biologic samples, we want you to be aware that if the samples are ever sent to other countries, the same laws and regulations that we have here might not apply. However, researchers wanting to test biological samples will have to apply to a committee of scientists that will decide if the test is appropriate. This committee will also require that a Research Ethics Board, like the one that helps protect you during this research project, will review and approve all future projects.

9. WHAT HAPPENS AT THE END OF THE STUDY?

We will ask for your permission to re-contact you in the future to invite you to provide additional samples or answer additional questionnaires. Any future involvement would be entirely optional. We ask you to notify us if your contact information changes over the years. We will also ask you for the contact information of a relative or friend in case we lose contact with you. Please ensure that you have their permission to provide us with their contact information.

After recruitment for this study is over, we will be keeping the blood, urine, saliva, toenail samples, along with the physical measures and information from the questionnaires to allow them to be used for future health related research. The samples and all of the information gathered for the study will be stored for 30 years, during which time they will be made available to researchers and may also be stored in a secure national storage facility that is being developed by the national study.

We expect to receive requests and, if approved, provide Canadian and International Researchers access to the data and samples. A Research Ethics Board, like the one that helps protect you during this research project, will review and approve all future projects before other researchers gain access to your samples. We may share the samples with other researchers, but we will not give the researchers any information that would allow them to identify you. We will always know which sample belongs to you, but other researcher will not.

General research results will be available on the Atlantic Path website at: www.atlanticpath.ca

10. WHAT ARE MY RESPONSIBILITIES?

As a study participant you will be expected to:

- Keep the study staff informed of your contact details for possible follow up.

11. CAN I BE TAKEN OUT OF THE STUDY WITHOUT MY CONSENT?

Yes. You may be taken out of the study at any time, if:

- Canadian Partnership against Cancer, Cape Breton District Health Authority Research Ethics Board or the Principal Investigator decides to stop the study.

You will be told about the reasons why you might need to be taken out of the study.

12. WHAT ABOUT NEW INFORMATION?

It is possible (but unlikely) that new information may become available while you are in the study that might affect your health, welfare, or willingness to stay in the study. If this happens, you will be informed in a timely manner and will be asked whether you wish to continue taking part in the study or not.

13. WILL IT COST ME ANYTHING?

Compensation

You will not be paid to be in the study. You can be reimbursed for gas mileage or transportation expenses up to a maximum of \$10.00 upon request.

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the Principal Investigator, the research staff, the study sponsor or involved institutions from their legal and professional responsibilities.

14. WHAT ABOUT MY RIGHT TO PRIVACY?

Protecting your privacy is an important part of this study.

When you sign this consent form you give us permission to:

- Collect information from you
- Access information from your administrative and health records including provincial Cancer Registries and Vital Statistics
- Re-contact you at a point in the future to see if you would be willing to answer further questions or provide additional samples
- Share information with the people conducting the study

- Share information with the people responsible for protecting your safety

Access to records

PATH computer support staff, who are responsible for maintaining all study databases, may see health and study records that identify you by name.

Other people may need to look at the health and study records that identify you by name. These might include:

- The Cape Breton District Health Authority Research Ethics Board (CBDHA REB)

The information they check may include physical measure values, biological samples, test and questionnaire results.

Use of records

The research team will collect and use only the information they need to complete the Study.

This information will include your:

- date of birth
- sex
- home address
- medical conditions
- medications
- the results of tests and procedures you had before and during the study
- information from study interviews and questionnaires

Your name and contact information will be kept secure by the research team at Dalhousie University. Your contact information will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study. Information collected for this study will be kept as long as required by the national study. This will be approximately 30 years.

Information collected and used by the research team will be stored by the research team in part at Dalhousie University and in part at Capital District Health Authority (CDHA). Information and samples collected may also be stored in a secure national data and sample storage facility that has been proposed by the national study. Information that can be used to identify you personally will be removed from the data or samples that are provided to the national facility. The Principal Investigator is the person responsible for keeping it secure.

You may also be contacted personally by Research Auditors for quality assurance purposes.

Your access to records

If you wish, you will be given a copy of the physical measures recorded at your initial assessment centre.

15. WHAT IF I WANT TO QUIT THE STUDY?

If you chose to participate and later change your mind, you can stop the research at any time. If you wish to withdraw your consent, please inform the study staff at 494-PATH (7284) or toll-free at 1-877-ATL-PATH (1-877-285-7284) or by writing to the coordinating centre. You will need to determine your desired level of withdrawal from the following options:

- “No further contact” – This means that staff of the PATH study would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously and to obtain and use further information from your health records.
- “No further use” – This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. PATH would destroy your samples (although it may not be possible to trace all distributed sample remnants) and would only hold your information for archival audit purposes. Your signed consent and withdrawal would be kept as a record of your wishes. Your samples will be discarded, but any data collected from testing your sample up until that point will remain part of the research.

16. DECLARATION OF FINANCIAL INTEREST

Canadian Partnership Against Cancer is paying the costs of conducting this study. The Principal Investigator has no financial interests in conducting this research study.

17. WHAT ABOUT QUESTIONS OR PROBLEMS?

For further information about the study, call the study team through the study information line.

Study Information Line:

Telephone: 494-PATH (7284) or toll-free at 1-877-ATL-PATH (1-877-285-7284)

18. WHAT ARE MY RIGHTS?

After you have signed this consent form you will be given a copy.

If you have any questions or concerns about the study, you may contact the Chair, District Research Ethics Board at 902-563-1833 (p).

In the next part you will be asked if you agree (consent) to join this study. If the answer is “yes”, you will need to sign the form.

PART C.

19. CONSENT FORM AND SIGNATURES

I have reviewed all of the information in this consent form related to the study called:

The Atlantic Partnership for Tomorrow’s Health

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

I agree to allow the people described in this consent form to have access to my health records for health-related research purposes

I understand that I may be re-contacted by PATH to answer some more questions and/or attend another assessment centre visit, but this is optional.

I give permission for long-term storage and use of my blood, urine, saliva and toenail clippings for health related purposes and relinquish all rights to these samples which I am donating to PATH.

I understand that none of my results will be given to me, except for some physical measurements taken at this visit.

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

_____	_____	____/____/____
Signature of Participant	Name (Printed)	Year Month Day*

_____	_____	____/____/____
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*

**Note: If filling in this form by hand, please fill in the dates personally*

I WILL BE GIVEN A SIGNED COPY OF THIS CONSENT FORM.

Thank you for your time and patience!