

CONSENT TO TAKE PART IN A RESEARCH STUDY
Participant Information

STUDY TITLE:	Sub-study to the Atlantic Partnership for Tomorrow's Health (PATH) Study – tap water sampling
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:	Dr Trevor Dummer, Dr John Murimboh, Mr Ron Dewar, Mr James Boxall
STUDY SPONSOR:	Canadian Cancer Society (CCS)

PART A.

RESEARCH STUDIES – GENERAL INFORMATION

1. INTRODUCTION

You have been invited to take part this sub-study linked to the Atlantic PATH research study that you have already agreed to take part in. Taking part in this additional 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

By taking part in this additional study you will be given the opportunity to receive information about the level of arsenic and other metals in your tap water. This additional study is not likely to provide you with any other information or benefits.

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?

In Nova Scotia around 45% of households receive their drinking water from a well. Because of the nature of the geology of Nova Scotia some water supplies have high levels of arsenic and other metals. When consumed in high quantities arsenic and some other metals can be harmful to health. We are collecting samples of tap water from Nova Scotian participants in the Atlantic PATH study and will analyze these to measure the level of arsenic and other heavy metals in the water. This information will provide us with a map showing the levels of arsenic and other metals in Nova Scotia.

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

You have been invited to take part in this sub-study because you agreed to take part in the Atlantic PATH study.

4. HOW LONG WILL I BE IN THE STUDY?

By agreeing to take part in this sub-study you will spend a further 10 minutes at the assessment centre and send us a sample of tap water from your home, which will take only a few minutes of your time.

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

We are collecting water samples from a selection of Nova Scotian residents included in the Atlantic PATH study, this will include all those who receive their water from a well and a sample of those who receive their water from a municipal source, up to a total of 12,000 individuals.

6. HOW IS THE STUDY BEING DONE?

This study is an additional sub-study to the Atlantic PATH project and includes the provision of one (1) sample of tap water.

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

If you decide to take part in the study we will provide you with a sterile plastic water sample bottle, water collection and return instructions. We will ask you to fill the bottle with a sample of your tap water and return the bottle to us. If you request it, we will provide you with the results of the analysis of your water sample; this will also include information on what you should do if a high level of arsenic, or certain other metals, is found in the water. Nova Scotia Department of Environment advise all Nova Scotia residents

with a well water supply to have their tap water tested for metals every two (2) years and by taking part in this sub-study you are being provided with this service at no cost to you.

8. ARE THERE RISKS TO THIS STUDY?

There are minimal additional risks to this sub-study beyond those already outlined in the Atlantic PATH consent form.

If you request it we will provide you with the results of the analysis of your water sample; however, the results of this testing may cause you some concern. We will provide information that will advise you what you should do if you the results of your drinking water analysis show high levels of arsenic or other metals.

9. WHAT HAPPENS AT THE END OF THE STUDY?

Your tap water sample will be tested for arsenic and other metals. These data will be stored alongside the existing Atlantic PATH data during which time they will be made available to researchers and may also be stored in a secure national data 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. 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 will not give the researchers any information that would allow them to identify you. We will always know which data belongs to you, but other researcher will not.

We will use these data to produce maps showing the levels of arsenic and other metals in Nova Scotia, and identify places where levels of these metals is high. You will not be able to be personally identified from any of these maps.

10. WHAT ARE MY RESPONSIBILITIES?

As a study participant you will be expected to:

- Follow the directions of the Principal Investigator
- Collect a sample of tap water from your home and return it to us.

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:

- The Canadian Cancer Society, 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?

New information on levels of arsenic and other metals will be obtained from the analysis of your tap water sample. If you request it, we will provide you with a copy of these results, although due to the nature of the testing of samples this may take several months.

13. WILL IT COST ME ANYTHING?

Compensation

There are no costs to taking part in this additional sub-study. You will be provided with a water sample bottle.

Research-related Injury

The aim of our research is to improve the public health. Sometimes, such research may result in findings or inventions that have value if they are made or sold. We may get a patent on these. We may also license these, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you would not receive any financial benefits.

14. WHAT ABOUT MY RIGHT TO PRIVACY?

Protecting your privacy is an important part of this study.

In addition to the consent you have already provided for the PATH study, when you sign this consent form you give us permission to:

- Receive a sample of your tap water supply
- Share this tap water sample with other investigators involved in the study for purposes of analysis of the water

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 which Atlantic PATH is part of. 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 collected may also be stored in a secure national data 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 results of the analysis of your tap water sample.

15. WHAT IF I WANT TO QUIT THE STUDY?

If you chose to participate in this additional PATH sub-study 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.

16. DECLARATION OF FINANCIAL INTEREST

The Canadian Cancer Society is funding 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 SIGNATURE PAGE

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

Sub-study to the Atlantic Partnership for Tomorrow’s Health (PATH) Study – tap water sampling

I have been given the opportunity to discuss this study.

All of my questions have been answered to my satisfaction.

I agree to provide the study with a sample of my home tap water.

I give permission for analysis of my tap water sample to measure levels of arsenic and other metals.

I have been given the opportunity to request that I receive a copy of the results of the analysis of my tap water sample.

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: Please fill in the dates personally*

I WILL BE GIVEN A SIGNED COPY OF THIS CONSENT FORM

Thank you for your time and patience!