

STUDY INFORMATION AND CONSENT DOCUMENT

Project Title: May Measurement Month 2023

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You are invited to take part in a global blood pressure screening project. Taking part in this study is voluntary. This document contains important information to help you make your choice.

1. What is this project all about?

This is a global research project. It involves taking blood pressure measurements and entering basic information from adult volunteers. Data collection will take place in more than 90 countries worldwide. Your local research team has partnered with the International Society of Hypertension for the May Measurement Month 2023 campaign. This project will enable us to combine data on adult blood pressure levels at a regional, national, and global level.

High blood pressure is a very common condition worldwide. Many people do not know they have high blood pressure and it can lead to heart disease, stroke, kidney disease, or even death.

With this screening project we plan to raise awareness of the importance of knowing your blood pressure. Research data will be used to motivate governments and other decision-making bodies to improve local blood pressure screening and treatment.

2. Why am I being asked to take part in this study?

You are being invited to take part because you are an adult aged 18 years or older.

3. How many people will take part in this study?

We aim to include over 1 million participants worldwide, making this the largest ever global blood pressure screening campaign. In the province of Newfoundland and Labrador, we expect to enroll about 350 participants.

4. What will happen if I take part in this study?

You will be expected to visit a community pharmacy research site on one occasion.

If you agree to take part, a pharmacist or pharmacy student will collect some basic information about you. This includes your country, city; when your blood pressure was last measured; your age and sex; whether you currently take blood pressure medication; whether you have diabetes or heart disease, smoke, or use alcohol. A blood pressure cuff will then be wrapped around your upper arm and you will be expected to remain seated for at least 5 minutes. Your blood pressure and pulse will be measured three times.

Your information will be entered into a secure electronic database. It will **not** include your name, date of birth, health care number, or contact information. Please note that the pharmacist and/or pharmacy

student who collected your information are not members of the research team and therefore, will not have access to this information once it has been submitted.

It will take about 15-20 minutes to take part in this study.

5. Are there risks to taking part in this study?

There are no physical risks to taking part in this research. You may feel discomfort in your arm when the pharmacist measures your blood pressure. This discomfort will go away as soon as the cuff is released.

You may find that your blood pressure is high, which may cause you some concern, but we will give you information on healthy lifestyle choices and refer you for further treatment, if necessary.

6. What are the possible benefits to taking part in this study?

You will know your blood pressure. We will provide you with dietary and lifestyle information to help keep blood pressure normal. If necessary, we will also advise you to consult with your physician or nurse practitioner for further measurements and treatment.

7. If I decide to take part in this study, can I stop later?

Taking part in this study is voluntary. You may refuse to take part, refuse to answer any questions or withdraw from the study at any point during your visit with the pharmacist. You do not need to provide a reason to withdraw from this study. However, once your visit with the pharmacist is complete, you will no longer be able to withdraw from the study.

8. What are my rights when taking part in this research study?

You have the right to receive all information that could help you decide about participating in this study. You also have the right to ask questions at any time and to have them answered to your satisfaction.

By consenting to take part in this study, it tells us that you understand the information about the study and agree to participate. You do not waive any legal rights by consenting to take part in this study.

9. What about my privacy and confidentiality?

We will not record your name, or any information that identifies you as an individual, anywhere. Your anonymity and privacy will be respected by all involved in this study, and your results will only be evaluated as part of population studies. Representatives from the Health Research Ethics Board may come to look at the study records under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines.

10. Will I be compensated for taking part in this study?

You will not be paid to take part in this study.

11. Who can I contact if I have questions about the study?

If you have any questions about taking part in this study, you can request to speak with the lead researcher, Dr. Tiffany Lee. You can also talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through the Ethics Office at 709-777-6974 or by email at info@hrea.ca.

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This is your copy of the Letter of Information and Consent to keep for your records.

My verbal consent to take part in this project means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information presented here.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free to withdraw from this study at any time up until the end of my visit with the pharmacist, without having to give a reason. This will not affect my care from the pharmacist.
- I understand that I cannot withdraw from the study once my visit with the pharmacist is complete.
- I understand that it is my choice to be in the study.
- I am aware of the risks of taking part in this study.
- I do not give up any of my legal rights by providing verbal consent.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this letter of information.
- I consent to providing demographic information about myself as well as information about my health and medications.
- I consent to have my blood pressure measured and recorded.
- I consent to having my non-identifiable information and blood pressure results used in any publication of research results.