
Effect of Reducing Ambient Traffic-Related Air Pollution on Blood Pressure: A Randomized
Crossover Trial NCT04029129

Informed Consent to Participate in Research

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Tufts University School of Medicine
Department of Public Health and Community Medicine

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Near Highway Pollution: From Research to Action Air pollution reduction study

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INTRODUCTION

Thank you for your willingness to learn more about this research project. The person administering this informed consent form is a member of the research team and will be happy to answer any of your questions. **Please don't sign this form unless all of your questions have been answered.**

WHY ARE WE DOING THIS STUDY?

We are trying to learn more about how effectively air filters reduce air pollution indoors. We also want to see if reducing air pollution indoors improves health.

This study is a collaboration between Tufts University, the Chinese Progressive Association, the Chinatown Resident Association, the Somerville Transportation Equity Partnership, the Metropolitan Area Planning Council, and Boston University.

This informed consent form explains:

- What the study is about.
- What you will need to do if you decide to take part in the study.
- The benefits and risks to being in the study.
- Your rights as a study participant.

WHAT WILL YOU DO IN THIS STUDY?

First, participating in this study is voluntary. This means that you can choose not to take part. Also, if you do participate, you are free to leave this study at any time by contacting the Principal Investigator, Doug Brugge (617) 636-0326.

To be eligible for this study you must be 40-75 years old. You are not eligible for this study if you:

- have a history of major cardiovascular illnesses (including heart attack, stroke, angina)

- have other serious health problems (current asthma or COPD)
- are taking anti-hypertensive medications
- smoke or live with a smoker
- work at a job with high combustion exposure (taxi/truck/bus driver, highway toll collector, etc.)
- do not speak English, Spanish, and Chinese.

Participating in the study involves three sessions at which you will visit a room at either Tai Tung Tenant Association in Boston Chinatown; MA or Mystic Activity Center in Somerville, MA. Each session will be 2 hours long and have filtered or not filtered air brought in to the room from outside. You will be asked questions to determine whether you are eligible for the study, to record basic demographic about you and about recent exposures you might have had that could affect your blood pressure.

Questions will include:

- Age, gender, education, income, residential address
- Where you spend your time during the day
- Exposure to smoking
- Occupational exposures
- Diet
- Medical conditions
- Exposures at home
- Salt intake
- Noise exposure
- Physical activity
- Stress

We will also measure your height and weight.

During each two hour session that you participate in the study you will wear a device on your fingertip to measure blood oxygen and heart rate. A blood pressure monitor will be placed on your upper arm and will inflate every ten minutes for the whole session. You will also be asked to wear sound canceling head phones so that noise does not affect your blood pressure.

You might also be asked to wear a second blood pressure monitor on your wrist that does not inflate, but measures blood pressure continuously.

WHAT ALTERNATIVE DO YOU HAVE TO PARTICIPATING?

You may choose not to participate. It is entirely up to you. If you choose to participate, you may decide to quit at any time.

WHAT ARE THE BENEFITS FOR TAKING PART?

Your participation may help us understand whether filters that reduce pollution can improve people's health. We will report the findings of the study to the community in presentations and printed materials. The reports will not say who participated and the reports will not include your personal data.

WHAT ARE THE RISKS IF I TAKE PART?

In each session you will breath air from the ventilation system that is either the same air that you already breath when you are outdoors or is cleaner because it has been filtered. Thus, the air in the room is not much different than, or is better than, the air that you breath at home, running errands or at work.

Measuring blood pressure and heart rate poses no physical risk, however, some people may experience stress from having their blood pressure taken.

The personal data we will collect is considered low risk. Thus, the main concern you might have is that we keep it confidential. All information collected for the study will be coded and stored on highly protected computers in locked offices to protect confidentiality.

Nevertheless, confidentiality cannot be absolutely guaranteed. Agencies responsible for protecting your health and identity, such as the Tufts Institutional Review Board (IRB), have the right to review the records from this study. These records may include the consent form that you signed. They will only do this to make sure that this study is being done properly and that we follow all the regulations and laws that apply. Your identity will be protected to the fullest extent of the law.

WHAT ARE THE COSTS?

There is no cost to you for participating in this study.

WILL I RECEIVE ANY PAYMENT?

You will be paid up to a total of \$150 in cash if you complete all three visits or \$50 per visit.

WHAT IF I HAVE QUESTIONS?

About the study_:

If you have any questions about this research study, you can ask a member of the research team for answers before you sign this form. Or, if you have questions after meeting with the team member today, you can call **Doug Brugge** at the Tufts University School of Medicine at **(617) 636-0326**.

About your rights as a research subject:

If you have any questions about your rights as a research participant in this study, you can call **Lara Sloboda** at the **Institutional Review Board** at **(617) 627-3417**.

PARTICIPANT'S STATEMENT:

I have read this consent form and I understand what I will do as part of this study. Someone from the research team answered any questions that I had.

I know that taking part in this study is voluntary, meaning that I can decide not to be in this study. I also understand that even if I agree to be in the study, I can leave at any time.

If I have any more questions about this research study, I can call **Doug Brugge** at the Tufts University School of Medicine at **(617) 636-0326**.

I understand that in the event I become ill or am injured as a result of participating in this research study, medical care will be provided to me.

If I have any questions about my rights as a research participant, I can call **Lara Sloboda** at the Institutional Review Board at **(617) 627-3417**.

I have been informed about this study. I know about the risks and benefits of taking part. By signing this form I know that I am giving my consent to be in this study.

I know that the study team will keep any personal information I give to this study confidential.

Date

Participant's Signature

I have fully explained to _____ the nature and purpose of this study. I have explained the risks of being in the study and I have answered all questions as best I can.

Date

Research Team Representative