Emory University Rollins School of Public Health
Consent to be a Research Subject
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Title: Atlanta Commuters Exposures (ACE) Study

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Sponsor: Centers for Disease Control and Prevention

Introduction

You are being asked to be in a medical research study because you have asthma or because you have no lung disease. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear
- Feel free to take home an unsigned copy of this form and take your time to about it and talk it over with family or friends

If you agree to join this research study, you will receive a copy of this consent form with your signature and the date, to keep. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. Nothing in this form can make you give up any legal rights. By signing this form you will not give up any legal rights.

Purpose

The purpose of this study is to learn more about how traffic pollution affects drivers' health.

A week before you start the study we will schedule a visit for you at Emory University to have tests done that will allow us to get an idea how healthy your lungs and heart are. This is called the baseline visit. On this day, you will be given a small device that measures your lung function called a peak flow meter and we will instruct you how to use it. Each morning leading up to your sampling commute day, you will perform a peak flow test. One day before the sampling commute day, you will also be given a personal sampler to keep with you for 24 hours. This device will capture what kind of pollution you are around on a normal day. You will also have a Holter monitor (a heart rate monitor) placed on you and record any health symptoms you may have on a diary

card. This process will be done once during the summer and again during the fall. If you decide after the first season that you do not wish to continue, you will not be required to complete the study.

The following morning research staff will come to your home at about 6:30 AM where you will do a few tests. These tests will reveal your lung and heart health status before you drive. The tests will all be described later in this form. A video camera and some equipment will be installed in your car. This equipment will record the levels of different kinds of pollution in your car. It will also record information about your car's engine, speed, acceleration, location and traffic congestion patterns. This entire process will take approximately 1 hour.

Once your car is ready, you will drive alone along a route the study staff has predetermined to Emory University. The entire 'scripted' commute will take two (2) hours. The research staff will follow you there. Once you arrive at Emory, the equipment will be removed from your car. Then you will repeat the tests you did at your home. You will repeat these tests every hour for 3 hours. Then your time in the study will be finished.

The researchers plan to enroll 20 people with asthma and 20 individuals without asthma who are 21 years old or older. Throughout the study, you will be asked to come to Emory University twice during each season for a total of four visits. The first time is for baseline testing and the second time will be when you drive with our equipment. Research staff will come to your home twice. The first time will be the day before you drive here with the research equipment. The second time will be the morning that you will drive here with the equipment.

You may not participate in this study if:

- You have been diagnosed with diabetes
- You have an implanted cardioverter-defibrillator or pacemaker
- You are currently taking digoxin or beta blockers for the treatment of high blood pressure or abnormal heart rhythms or heart beats
- You have been diagnosed with a non-asthma lung disease
- You have a FEV1 (a lung function measurement) value less than 70% of your predicted volume
- You have severe asthma that will not allow you to temporarily stop taking some of your asthma medicines
- You smoke tobacco products or are regularly exposed to second-hand tobacco smoke within the previous year
- You do not possess a valid driver's license or have legal access to a properly insured vehicle
- You are currently pregnant. If you become pregnant during the study, you must notify study personnel and you will be removed from the study.

Procedures

All procedures in this study are research procedures. None of them will cost you or your health insurance company anything. They will all be paid for by the Study Sponsor.

1. **Health and Exposure Questionnaires:**
   You will be asked questions about your health. These questions will focus on your heart and lungs but will ask about any other conditions you may have. If you are a female, you will be asked if you are currently pregnant. If you are, you will not be allowed to continue with the study. You will also be asked questions about your home, daily routine, or other things that may lead to increased exposure to air pollution. These forms will include detailed questions about the type of flooring, how often you

clean and how much time you spend in each room. They will also ask you about your daily route to work and the conditions there. These questionnaires will be asked at your baseline visits to Emory.

2. **Vital Signs Testing:**
   The study staff will measure your height and weight and test your blood pressure, blood oxygen level, heart rate and temperature. These measurements are painless and will be very similar to what happens during a regular visit to the doctor. Vital signs will be tested twice during the study.

3. **Bronchodilator (BD) withhold:**
   You will be asked not to take certain medicines called bronchodilators on four occasions during the study. This is done so that your lungs can be tested when they are not being helped by your normal medicines. If you do not have asthma this will not apply to you. You will receive clear instructions about which medicines to stop and when. The longest you would have to stop taking any medicine is two days before your visit. Most medicines only have to be stopped for less than a day.

4. **Exhaled Nitric Oxide (eNO):**
   You will take a deep breath in and blow out slowly and evenly into the mouthpiece of a portable machine. A member of the study staff will show you how to do it right. The machine will measure the amount of nitric oxide in your breath. Nitric oxide shows us how inflamed your lungs are. You will do this test a total of twelve times in the study.

5. **Exhaled Breath Condensate (EBC) and saliva collection:**
   You will breathe normally into a plastic tube for 15 minutes. The top of the tube will be cooled with a metal sleeve around it. This makes your breath condense and form liquid droplets in the plastic tube. The collected liquid will be tested for ions, acids and other chemicals that are in your lungs. You will do this test a total of twelve times in the study. Each time you do this you will also spit a small amount of saliva into a cup or tube.

6. **Spirometry:**
   This is a standard test of lung function. To perform this test, a technician will instruct you to take a full, deep breath in and blow out as quickly and completely as you can into a mouthpiece connected to a computer. This effort will be repeated three to eight times until we have three repeatable tests. This test will be repeated a total of twelve times during the study. Four out of the six times we will also give you 4 puffs of an albuterol inhaler and test your spirometry again after waiting 15 minutes. This is done to test how reactive your lungs are.

7. **Blood Draw:**
   A blood sample of about two-thirds of a tablespoon (10mL) will be collected and used for several analyses. One analysis is a complete blood count (CBC). The rest of the blood will be used to test for markers of inflammation found in the blood. Your blood will be drawn once at baseline, once immediately before your commute and once two hours after your commute for a total of three times for each sampling commute and six times during the entire study.

8. **Electrocardiogram (ECG or EKG):**
   A test will be conducted at your baseline visit to check for any abnormal heart rhythms. A technician will place a total 10 to 12 leads (small sticky pads with metal connectors) on your chest, wrists, and lower legs. These will be connected together by wires that lead to a machine that will display the results on graph paper. This test will only occur once during the study.

9. Heart Rate and Heart Rate Variability Monitoring:

Your heart rate will be monitored starting 24 hours before your scheduled commute to Emory. A technician will come to your home and apply a 5 lead Holter monitor. If you are a male, your technician may be male or female. If you are a female, your technician will be a female. This is a device that monitors your heart rhythms in a similar manner to the EKG which was described above. This device stores the information rather than directly printing it out. The leads will be connected by wires that connect to a small device that will clip on to your belt. The device will take a reading of your heart rhythms every five minutes until you finish the study the next day. You will wear the Holter monitor for a total of about 30 hours before and during each of your two commutes.

10. Personal Exposure Sampling:

You will receive a device that will be used to monitor your exposure to particle pollution for the 24 hours before your scheduled commute. This will be delivered at the same time the technician comes to apply your Holter monitor. You will keep this device near you throughout the 24 hours before each of your commutes. This is done to see how many particles you are exposed to during your normal daily routine.

11. Symptom and time activity diary:

Starting at the same time as your baseline visit, you will be asked to keep a diary of any asthma-related symptoms that you have during the 24 hours before each of your commutes. You will also record any major activities that happen during those 24 hours. This information will be used to interpret some of the information gathered by the Holter monitor and the personal exposure sample.

12. Commute to Emory:

Your car will be outfitted with a video camera and several devices which will monitor your engine information, location, speed, acceleration, traffic conditions and the pollution in your car. To do this, study staff will come to your home at about 6:30 AM on the morning of your scheduled commute. Once your car is ready you will follow specific directions to Emory University where the equipment will be removed from your car. You will commute to Emory twice during the study.

Timeline of study procedures:

COMMUTE

Baseline Visit (1 week pre-commute)	**24 hours pre-commute**	**pre-commute**	**post-commute**	**1 hour post-commute**	**2 hours post-commute**	**3 hours post-commute**
informed consent	personal exposure sampling	Car equipped	Equipment removed			
health and exposure questionnaires	symptom and time activity diary	|———	———	continuous ———	———	———|
BD withhold[a]		BD withhold[a]	|———	continuous ———	———	———|
spirometry		Spirometry	spirometry	spirometry	spirometry	spirometry
eNO		eNO	eNO	eNO	eNO	eNO
EBC/saliva		EBC/saliva	EBC/saliva	EBC/saliva	EBC/saliva	EBC/saliva
Blood Draw		Blood Draw		Blood Draw		
ECG	Holter monitor |———	———	———	continuous ———	———	———|
Vital Signs						

Risks and Discomforts

If you have asthma your condition may not get better, and it may even get worse, as a result of your being in this study. The most common risks and discomforts expected in this study are:

- If you have asthma, you may experience an increase in asthma symptoms when you briefly stop taking your asthma medicines. However, if symptoms become too severe for your comfort please take your rescue medication and/or your regular medication as directed by your doctor and call study staff immediately.

- Performing spirometry may cause chest tightness, shortness of breath, coughing and dizziness. These symptoms are caused by the effort of blowing out quickly and go away quickly.

- Taking albuterol may make your heart race, make you feel jittery or nervous and can increase your blood pressure. These feelings are temporary and should be gone within 15-30 minutes.

- Having your blood drawn may cause pain at the site of skin puncture and also may cause bleeding or bruising of the skin. You may also experience light-headedness.

- The leads from the Holter monitor may cause red, irritated skin.

- Waking up early to be tested for the study may make you feel tired or uncomfortable.

The less common risks and discomforts expected in this study are:

- Having your blood drawn may cause infection.

- Taking albuterol can cause nausea or headache. If these occurred, they would be temporary and be gone within 15-30 minutes.

Rare but possible risks include:

- Having your blood drawn can rarely cause fainting.

- There is the rare possibility that you may have a car accident during your commute to Emory. However, this risk will be no greater than at any other time that you are driving your car in traffic. The monitoring equipment will be installed in a way that will not impair your ability to drive as you normally would.

- Increased exposure to traffic-related pollution represents an additional risk to study participants. Previous studies of this type have observed modest yet asymptomatic increases in biomarkers of inflammation and oxidative stress. Baseline visits for the subjects will be conducted prior to completing the driving protocol that are designed to prevent those whose health may be too poor to complete a commute from doing so. During the commute the participant will have study staff contact information in the event that there is any traffic or health related problem.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it so you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. Your asthma will not improve while you are in this study, and it may even get worse. This study is designed to learn more about the health effects of air pollution. The study results may be used to help other people in the future.

Token of Appreciation for Participation

We offer a token of appreciation for your time and interest. You will be provided $150 for each period from pre-commute monitoring until the end of the sample collection period. If you complete the study, you will be provided a total of $300 for two completed commute periods. If you do not finish the study, a token of appreciation will be provided for the visits you have completed.

Other Treatment Outside this Study

This is not a treatment study. You are free to choose not to take part in it.

Confidentiality

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies, Emory employees overseeing proper study conduct may look at your study records. Study sponsors may also look at your study records. These offices include the Office for Human Research Protections, the Centers for Disease Control and Prevention (CDC), the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research. Emory will keep any research

records we produce private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order or produced in response to a subpoena or a request for production of documents unless a Certificate of Confidentiality is in place for this study.

If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient you do not have one. Please note that an Emory Healthcare medical record will **not** be created for you just because you are in this study.

Emory Healthcare may create study information about you that can help Emory Healthcare take care of you. For example, the results of study tests of procedures. These useful study results **will** be placed in your Emory Healthcare medical record. If you agree to be in this study, a copy of the consent form and HIPAA patient form that you sign will be placed in your Emory Healthcare medical record. Anyone who has access to your medical record will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA Privacy Rule. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory does not control results from tests and procedures done at other places. So these results would not be placed in your Emory Healthcare medical record. And they will not likely be available to Emory Healthcare to help take care of you. Emory also does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. So if you decide to be in this study, it is up to you to let them know.

The researchers will review the results of certain study tests and procedures **only** for the **research**. The researchers will **not** be looking at these results to make decisions about your personal health or treatment. For this study, those things include: health and exposure questionnaires, EBC/saliva results, research-only blood tests, personal exposure sampling and the symptom and time activity diary.

In Case of Injury

If you get ill or injured from being in this study, Emory would give/arrange for you to have urgent health care. Here we explain who would pay for this health care:

Would Emory Pay? Emory has not set aside any funds to pay for urgent health care. Also, Emory has not set aside any funds to pay you if you become ill or injured from being in this study. The only exception to this policy is if it is proven that the negligence of an Emory employee directly caused your injury or illness. "Negligence" means the failure to follow a standard duty of care.

Would the Study Sponsor, the CDC, Pay? The CDC has not set aside any funds to pay for urgent health care. Also the CDC has not set aside any funds to pay you if you become ill or injured from being in this study. If you believe you have been injured by this research, you should contact Jeremy A. Sarnat, Sc.D. at 404-712-9725.

Neither Emory nor the CDC will be responsible for damages to your car or for repair costs if you have a car accident during the study.

Costs
There are no costs to you or your health insurance provider for any of the procedures that will be performed in this study. The Study Sponsor will pay for all the procedures in this study.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The study doctor and sponsor also have the right to take stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- Medical conditions found by research procedures prohibit you from safely completing the study.
- or for any other reason.

Questions
Contact the study coordinator, Eric Hunter at 404-712-8381 or eric.hunter@emory.edu:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.

Consent
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

_____
Name of Subject

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

Specimen Banking for Genetic Studies. The study team is collecting blood in this study. It is possible that some of your blood may be used for future testing and/or to evaluate your genes (DNA) that may be related to asthma or response to air pollution. No other genes will be studied. DNA is the genetic material contained in all the cells of your body, including blood cells and cells in your saliva. Subjects may decline genetic banking and still participate in the main study.

The information that is obtained from the analysis of your blood may be used scientifically and may be used by the sponsor in other research. The analysis of your blood samples may contribute to the creation of new diagnostic tests, new medicines or other uses that may be commercially valuable to the sponsor. You will receive no financial benefits and may not receive any health-related benefits from such developments. You do not give up ownership of you tissue; you give up ownership of any technology that may be developed from it.

The research investigators involved with this study and any other individual who may have access to the subject's bodily fluids, substances or tissues are not authorized to and are forever prohibited from using this material for any attempt at cloning a human being.

Work with your blood and DNA would be done at Emory University, Georgia Institute of Technology or the Centers for Disease Control and Prevention. Your name and participation in these studies will be held strictly confidential. Your genetic samples will be identified only by an ID number and not by your name. No genetic analysis will be done other than that associated with asthma, response to air pollution, and these samples will not be given to any other investigators. Any identifying data is kept in a locked drawer or in a password protected computer file. Unless you disagree (see below), the Principal Investigator will keep a private list that links your sample code with your name, allowing him/her to know which samples were collected from you. You can request that we not keep any information linking your name with your sample, but please understand that once we lose the ability to know which sample(s) came from you, we also lose the ability to destroy your samples upon request, or to respond to any future requests you may make regarding results or new information. Only the principal investigator, study coordinator, and data manager at Emory University will have access to the numeric code that identifies you by name. Results will NOT be put in your medical records. No HMO or insurance company will ever be allowed access to genetic results. The laboratory that is processing your DNA is a research facility and does not have the ability to provide genetic test results or genetic counseling. Genetic information about you or other information obtained from your sample will not be given to you, your family, or your doctor. You may change your mind and withdraw consent for the use of your blood at any time by contacting Jeremy A. Sarnat, Sc.D. at 404-712-9725 or jsarnat@emory.edu. However:

a. Results from research studies using your samples may be presented in publications and meetings but individual names will not be identified.
b. Absolute confidentiality cannot be guaranteed as the U.S. Department of Health and Human Services has the right to inspect your medical records relating to the research for the purpose of verifying data. Information on the subjects is released only to describe the features of the volunteers that take part in this study to the National Institutes of Health.
   In order to safeguard records, 1) Only authorized users will have access to records, 2) the records will be maintained in offices that are locked when not in use, and 3) access is strictly controlled. The records collected in this study will be subject to the Privacy Act (see separate HIPAA authorization). Records will not be disclosed to any person or agency unless the individual who the records are about provides a written request or prior consent. The request

should be made in writing to the Privacy Act Coordinator, NHLBI, NIH, Building 131, Room 5A10, 9000 Rockville Pike, Bethesda MD 20892.

Risks. There is a potential risk to insurability and employability based on the results of the genetic testing. However, results **will not** be placed in your medical record and we will not reveal this information to any insurance agencies or employers.

Benefits: Although your participation in this study may not directly help you or your relatives, the results of this research project should help us understand more about asthma and/or responses to air pollution.

Please initial one choice below:

- I do agree to allow my stored blood samples to be used for future testing, including DNA (genetic) testing: _____ (initials)
- I do not agree to allow my stored blood samples to be used for future testing, including DNA (genetic) testing: _____ (initials)

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

If you would like to volunteer for this research, please sign below.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____ _____
Signature of Person Obtaining Authorization Date