UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: GLACIER Study 2- Joint Initiative Harmonized Protocol
1.2 Company or agency sponsoring the study: United States Environmental Protection Agency
1.3 Names, degrees, and affiliations of the researchers conducting the study:
   Robert D. Brook MD, Internal Medicine/Cardiology, University of Michigan
   Robert L. Bard, MA, Internal Medicine/Cardiology, University of Michigan
   Susan Lustig, Internal Medicine/Cardiology, University of Michigan
   Lu Wang, School of Public Health, University of Michigan
   Jason Knight, Internal Medicine/Rheumatology, University of Michigan
   Louise O’Brien, Department of Neurology, University of Michigan
   Subramaniam Pennathur, Internal Medicine/Nephrology, University of Michigan
   Eugene Chen, Internal Medicine/Cardiology, University of Michigan
   Masako Morishita, School of Public Health, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The purpose of this study is to investigate the contribution of the quality of the air that you breathe to the levels of your cholesterol and to investigate whether there is a link between pollutants and cholesterol.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may participate if you are generally healthy age 18-50 years old. However, you may be obese if you meet all the remaining criteria.

You may NOT participate if you:

a.) Smoke or anyone in your household smokes
b.) Have not lived at your current residence for at least 6 months
c.) Plan to travel more than 50 km (about 31 miles) from your home during the study testing
d.) Have elevated blood pressure or blood sugar at the screening visit.
e.) Are pregnant or have a positive pregnancy test at the screening visit
f.) Have a history of cardiovascular disease such as: coronary artery disease, stroke, or peripheral vascular disease.
g.) Have risk factors for cardiovascular disease such as high blood pressure, diabetes, or high cholesterol.
h.) Take medications for diabetes, high blood pressure, cholesterol, or obesity. You may not take fish oil, daily multivitamins, daily anti-oxidants or folate, or daily non-steroidal anti-inflammatory medications during the past 6 months.

i.) Have asthma, severe allergies, or lung disease like chronic obstructive pulmonary disease (COPD).

j.) Have chronic kidney disease or cancer.

3.2 How many people (subjects) are expected to take part in this study?
50 healthy adults, including 25 obese adults.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Screening Visit:
*The study will be explained to you and we will discuss your medical history and take your blood pressure and height and weight.

*You should fast for at least 8 hours (nothing to eat or drink except water), we will do a blood test to measure your blood sugar by poking your finger. The total amount of blood at this visit will be less than 1 milliliter (less than 1 teaspoon).

Study Blocks: This 2-day study “block” will be repeated twice (with a 1-4 week break between blocks).

Day 1: “Exposure monitoring”, “Health outcome testing”, and some “Overnight testing” (see table below)

Day 2: “Health outcome testing”

“Health outcome testing”:
  a. Ultrasound: The function of your arm blood vessel will be tested by placing your forearm in a blood pressure cuff while you are lying flat and resting. The cuff will be inflated to a level above your blood pressure stopping blood flow to your forearm and hand for 4 minutes. Then the cuff will be released, returning blood flow to your arm, while an ultrasound probe is placed on your upper arm and measures the blood vessel response.
  b. Holter: Stickers (electrodes) will be placed on your chest while you rest to measure your heart rate and rhythm, this will take about ten minutes.
  c. Blood will be drawn from a vein for markers of inflammation and cholesterol function. The total amount of blood at each of these 3 exposure visits will be up to 45 milliliters (approximately 3 tablespoons).

“Overnight testing”:
  a. Pollution monitor: You will be given a monitor and you are to keep it with you for the two days of the study wherever you go. While sleeping you can leave it next to you. This monitor samples the air around you. The monitor can be strapped to your waist with a belt or fanny pack we will provide.
  b. WatchPAT: This will monitor your breathing while you sleep. You will be given a monitor to put on your wrist when you go to sleep that has wires leading to sensors that go over two of your fingertips.

4.2 How much of my time will be needed to take part in this study?

Table: 

Table: Sample study time commitment.
5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- There are unknown risks to a pregnant woman, therefore, women of childbearing potential may not participate and will have a urine pregnancy test during the screening. Women of child-bearing potential must use adequate birth control (e.g. hormonal contraceptives such as the pill, condom, diaphragm, IUD, or abstinence.

The most common side effects (occurring in more than 10% of patients) are:

- Pain, bruising, and occasionally infection or feeling faint during blood draws.
- Pain, numbness/tingling, and bruising of the arm may occur during the blood vessel function tests with the ultrasound and the blood pressure measurement. There is no risk for permanent or long-term harm from these procedures. Any side effect or discomfort is rapidly and completely reversed within a few minutes after release of the blood pressure cuff. There are no reports of any harm to any patient by this technique during the past 10 years.
- Some irritation of the skin may occur from the adhesive that holds the electrodes onto the skin from the Holter monitors. This risk is uncommon and usually minor.
- There is a possibility of not sleeping well while wearing the WatchPat monitors because it interferes with your routine.
- There is a risk of breach of confidentiality which is rare and the investigators keep your information in secure computers with access limited to only those involved in the study. Your identity is protected within the research database and your identity is only linked in a separate document.

The researchers will try to minimize these risks by having only trained, experienced individuals participate in your testing and by monitoring your responses and complaints throughout the study.
As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies? No
**Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies.** You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. Others may not benefit or may benefit by the knowledge of the health effects of the air they breathe.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
This study is voluntary, you may choose to participate or not participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is unlikely to be any harm associated with leaving the study before completion.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:
- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers’ number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Yes, you will be paid a total of $200 if you complete the two study blocks. Study payments will be pro-rated in the event the entire block is incomplete. You will not be paid for the screening visit. You will be paid the appropriate total in one payment using a payment voucher which you take to the University cashier for payment in cash.

8.3 Who could profit or financially benefit from the study results?
There are no financial benefits associated with the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy? Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The initial questions you answer on the website and provide to the study team will only be used to schedule your appointment and is not a part of your research record.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
• University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
• Study sponsors or funders, or safety monitors or committees, may need the information to:
  o Make sure the study is done safely and properly
  o Learn more about side effects
  o Analyze the results of the study
• Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
• The researchers may need to use the information to create a databank of information about your condition or its treatment.
• Information about your study participation may be included in your regular UMHS medical record.
• If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
• Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
• To avoid losing study results that have already included your information
• To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
• To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan “Notice of Privacy Practices”. This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
• Obtain more information about the study
• Ask a question about the study procedures or treatments
• Talk about study-related costs to you or your health plan
• Report an illness, injury, or other problem (you may also need to tell your regular doctors)
• Leave the study before it is finished
• Express a concern about the study
  Principal Investigator: Robert Brook  
  Mailing Address: 24 Frank Lloyd Wright Dr, Lobby M Ann Arbor, MI 48106  
  Telephone: 734 998-7956
  Study Coordinator: Robert Bard  
  Mailing Address: 24 Frank Lloyd Wright Dr, Lobby M Ann Arbor, MI 48106  
  Telephone: 734 998-7956

You may also express a concern about a study by contacting the Institutional Review Board listed below.  
University of Michigan Medical School Institutional Review Board (IRBMED)  
2800 Plymouth Road  
Building 520, Room 3214  
Ann Arbor, MI 48109-2800  
Fax: 734-763-1234  
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.  
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:
• This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)
12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with ________________________. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: ______________________________________________________________________

Signature: _________________________________________________________________________

Date of Signature (mm/dd/yy): ______________________

For use only if required by sponsor:

Date of Birth (mm/dd/yy): __________________________

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: ______________________________________________________________________

Title: ____________________________________________________________________________

Signature: _________________________________________________________________________

Date of Signature (mm/dd/yy): ______________________