University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
(Screening for metabolic syndrome criteria)
Adult Subjects

Medical IRB Study: 04-1677 (formerly GCRC #2067)
Consent Form Version Date: April 7, 2010
Title of Study: Physiological changes in adults with metabolic syndrome exposed to concentrated Chapel Hill ultrafine air particles

Principal Investigator: **Robert Devlin, PhD (EPA) Candice Bailey, PhD (EPA) Martha Sue Carraway, MD (EPA)**

UNC-CH Department: NA

Phone number: 919-966-6255

Co-Investigators:

EX.6

Sponsor: United States Environmental Protection Agency

You are being asked to take part in a research study. The investigators listed above are in charge of the study; other professional persons may help them or act for them.

What are some general things you should know about research studies?

Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your participation is voluntary. You may refuse to participate, or may withdraw your consent to participate in any study at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your doctor. If you are a patient with an illness, you do not have to participate in research in order to receive treatment.

Details about this particular study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

Participant's initials_____

The purpose of this screening session is to determine whether you meet the criteria for having metabolic syndrome. A person having three of the following five criteria meets the definition of metabolic syndrome:

- Waist circumference: Men >102 cm (>40 in)
  Women >88 cm (>35 in)
- Triglycerides: ≥150 mg/dL
- HDL cholesterol: Men <40 mg/dL
  Women <50 mg/dL
- Blood pressure: ≥130/≥85 mmHg
  OR
  have a history of high blood pressure requiring medication
- Fasting blood sugar: ≥100 mg/dL and ≤126 mg/dL

For your safety and well-being, you will be excluded from further participation if you have a fasting blood sugar greater than 126 mg/dl or a blood pressure greater the 160/100. If we find either of these to be true, we will suggest that you contact your personal physician for follow-up. In addition, we will be running other general blood tests, similar to blood tests you would get during a physical exam, to further ensure that you are healthy enough to participate in this study. These blood tests will be discussed with our physician during your physical exam, assuming you qualify for this study. With your written approval we will provide your physician with laboratory test results. If you do pass this screening, you will be scheduled for a physical exam to further determine if you qualify for this study. During this physical, you will have a chance to discuss the results of the blood tests completed today.

How many subjects will participate in this study?

If you decide to participate, you will be one of approximately 30 participants in this study.

How long will your participation last?

Participation in this portion of the study will last for approximately 15 minutes.

What will happen if you take part in the study?

For this portion of the study, you will be required to provide a blood sample (< 1/8 of a cup), have your blood pressure measured, and measure your waist size.

Are there any reasons you should not participate?

You should not participate in this portion of the study if you are not a candidate for the subsequent portions. The inclusion and exclusion criteria will be described. Briefly, you should not participate if you are pregnant. You need to be a non-smoker for at least 3 months prior to the study and/or smoked only a little earlier in life. There are several medical conditions that may prevent you from participating in this study including active allergies, diabetes, need for a pacemaker, a previous heart attack or coronary bypass surgery, dialysis treatment, or the need for supplemental oxygen. The investigators and medical staff will explain other potential exclusionary conditions in detail to you.

What are the possible risks or discomforts?

Participant's initials_____

The risks associated with taking blood samples are considered minimal. A qualified member of the staff will draw the blood and a blood draw could cause bruising or some minor pain, which usually resolves quickly. Also, a rare complication is skin infection or an infection of the vein in which the blood has been drawn. The risk of getting an infection is minimized by the use of aseptic technique. If you do have signs of infection at the site (redness, warmth, painful skin, and swelling) after completion of the procedure, you will need to contact the EPA medical station.

Using a blood pressure cuff to measure blood pressure may cause mild discomfort and unusual sensations such as tingling and numbness.

In addition, there may be uncommon or previously unrecognized risks that might occur. If you do notice any unusual symptoms occurring during the study you should call the EPA medical station to report them.

What are the possible benefits?

There are no direct benefits to you for completing this portion of the study. However, you will receive some blood work, blood pressure measurements, and, you will qualify for further participation in the study, provided these measurements fall within the necessary limits.

What if we learn about new risks during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

No participants will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-CH will take all steps allowable by law to protect the privacy of personal information.

Will you be paid for participating?

You will receive $25 for completing this screening procedure. Participants traveling from outside of Chapel Hill will be reasonably compensated for travel and parking costs will be paid for all participants choosing to drive to the HSF.

Payments totaling more than $600 in a year from a single or multiple EPA studies will be reported to the IRS.

Will it cost you anything to participate?

The U.S. EPA will pay the costs of this research. You will not be billed for any procedures. However, we may recommend that you seek follow up care from your own health care provider if abnormalities are found. Such care is entirely at your own expense. EPA will not provide reimbursement for any follow up care.

What will happen if you are injured by this research?

All forms of medical research, diagnosis, and treatment involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due

Participant's initials_____

to participating in this study. If you are injured from participating in this study the researchers will assist you in obtaining appropriate medical treatment but any costs associated with the treatment will be billed to you or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to compensate you for any such complications or injuries or for related medical care. However, if you develop an injury or illness determined by the on-duty physician to be due to your participation in this research, the EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. seq., provides for money damages against the United Sates when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence. If a research related injury or illness occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919.966.6217.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have further questions regarding this study, you should call one of the listed investigators:

Robert Devlin, PhD 919-966-6255
Candice Bailey, PhD 919-966-8373
Martha Sue Carraway, MD 919-843-5948
Mike Schmitt, MSPH 919-966-0647

If you feel a research-related injury has occurred, please contact the HSF medical station 919-966-6232 or one of the investigators listed above. In addition, you should contact the Environmental Public Health Division Human Research Officer and Director of the National Health Effects and Environmental Research Laboratory Human Research Protocol Office at 919-966-6217.

What if you have questions about your rights as a subject?

This research has been reviewed and approved by the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill. If you have any questions or concerns regarding your rights as a research participant, you may contact the UNC Medical IRB at (919) 966-1344 and the Environmental Public Health Division Human Research Officer and Director of the National Health Effects and Environmental Research Laboratory Human Research Protocol Office, at 919-966-6217.

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Participant's Agreement:

I have read the information provided above. I voluntarily agree to participate in these screening tests.

______________________________________ ________________
Signature of Research Participant Date

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Printed Name of Research Participant

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent

 Participant's initials________