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University of North Carolina at Chapel Hill
Consent for Storing Biological Specimens With Identifying Information

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IRB Study # 06-0548
Consent Form Version Date: September 10, 2009

Title of Study: Mechanisms by which air pollution particles exacerbate asthma in older adults with mild asthma

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[redacted]

Faculty Advisor:
Funding Source: US Environmental Protection Agency

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What are some general things you should know about this research study?

Research studies are designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Research with blood, tissue and/or body fluids (specimens) can help researchers understand how the human body works. Research using specimens can also answer other questions. Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat diseases. In the future, some research may help to develop new products, such as drugs.

You may refuse to allow us to have or store your specimen. If you are a patient with an illness, you do not have to be in the research study in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers 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?

Recent reports have shown that people with asthma that have a particular gene, known as the GSTM1 null gene, are more susceptible to the effect of air pollutants such as ozone and diesel exhaust. The purpose of this research study is to learn if subjects who have mild asthma and the GSTM1 null gene also have an increased response (changes in lung function and increases in lung cells collected from sputum) compared to subjects with asthma and the GSTM1 sufficient gene following exposure to concentrated fine and ultrafine air pollution particles. Studies have shown that asthmatics represent a particularly sensitive group of individuals with older adults representing a significant subset of this group which needs to be studied for their response to particulate matter (PM) and ozone. Older adult subjects with mild asthma will be recruited to undergo PM challenge at approximately 200 microgm/m^3 for 2 hours at rest.

PM exposure has been extensively studied in our laboratory and causes a range of changes in lung function and sputum in normal subjects. We will be collecting samples which will help us to further study this condition. In order to do so, we will need to collect and store blood and alveolar lavage cells. DNA will be isolated from blood samples for the purpose of determining your genotype prior to the exposure sessions for the presence or absence of the GSTM1 gene. We may also further genotype the DNA samples at a later time for other genes, however this genotyping will be limited to genes associated with air pollution exposure. We may also isolate RNA from lung cells and the blood for genetic analysis to see if there is a genetic difference between pre and post PM exposures. Blood samples will also be collected in order to look for but not limited to indicators of inflammation due to the PM exposure.

All samples will be stored where only project members will have access to the samples. There is a need to store samples in such a repository because this will be an ongoing study where samples from subjects will be collected over an extended period of time. Storing of samples allows for all samples to be processed at the same time and also allows our scientist the opportunity to further study these samples with as yet unknown questions and techniques.

How will the specimen be collected?

Samples will be collected in the following manner.

- Lung cell collection. Cells will be collected from the airways and airspaces of the lung by bronchoscopy with bronchoalveolar lavage and brush biopsy. (This procedure is explained in separate consent.) Fluid will be collected into specimen tubes and placed on ice. The cells will be separated from the fluid by centrifugation, and both samples may be processed immediately, or frozen for later analysis.
- Blood collection. You will have up to 80 cc (about 5 tablespoons) of blood per sample collected from an arm vein by our trained nursing staff. The blood will be placed into specially designed blood collection tubes which allow separation of the fluid and cell portions of blood. Those samples may be processed immediately, or be frozen for later analysis.

What will happen to the specimen?
Samples will be stored at the U.S. Environmental Protection Agency Human Studies Facility located in Chapel Hill, North Carolina. Only project members of the study will have access to the samples. Blood samples will be collected in order to look at but not limited to, indicators of inflammation due to the air pollution exposure. Specimens may be released to other investigators if there is a need to analyze samples with equipment that is not located at our facility.

What are the possible benefits to you?
Benefits to you are unlikely. These studies (current and future) may provide additional information that will be helpful in understanding asthma and how environmental factors affect the disease.

What are the possible risks or discomforts involved with being in this study?
This study might involve the following risks and/or discomforts to you:

1. Blood sampling will be performed by well-trained personnel, and entails only a risk of mild discomfort with the infrequent possibility of lightheadedness, fainting, infection or developing a bruise.

2. Bronchoscopy may induce cough, wheezing, shortness of breath, or fever. Using albuterol prior to the induction reduces the risk of bronchospasm (tightening of the airways) in people with asthma.

3. Risk of breach of confidentiality is minimal. For the mild asthmatic subject, it is conceivable that an employer or insurance company could learn of the diagnosis if you required medical intervention as a result of participating in this study. You will be assigned a study number which will be used for data – not your name. The study number is all that will be entered into computer databases. All paper files which may contain your name or screening number are secure in the EPA building which has limited access 24 hours/day. A numeric coding system will be used to ensure that you cannot be directly identified from the samples alone.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers

Will there be any cost to you for storage of the specimens?
There will be no cost to you for the storage and use of the specimens for research purposes.

Who owns the specimens?
Any blood, body fluids, or tissue specimens obtained for the purpose of this study become the exclusive property of The U.S. Environmental Protection Agency. The researchers may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will your privacy be protected?
You will be given a study code number. All electronic documents will only have that number. The paper records that the coordinators and medical doctors use may have your name. Your information can be linked to your personal information by the study number, however only study personnel have access to your personal information. Paper records which use your name are kept in a locked file cabinet in the EPA Medical Station of the Human Studies Facility. The Medical Station is locked when not attended by study staff, and the EPA Human Studies Facility has limited access to authorized individuals only, 24 hours/day for 7 days/week. Samples used for genetic analysis will be stored at the EPA Human Studies Facility.
Research studies may be done at many places at the same time. Your personal identifying information will not be sent to outside researchers.

No one 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, U.S. EPA and/or UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants.

In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive study results of future research involving your specimens?
Most research with your specimens is not expected to yield new information that would be meaningful to share with you individually. In rare cases, you may be offered the opportunity to receive information about the results of research in which the specimens were used (for example, findings that would affect your medical care).

Can you withdraw the specimens from the research study?
If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. You may also contact the Institutional Review Board, University of North Carolina at Chapel Hill, 919-966-3113, Medical School Building 52, CB 7097, Chapel Hill, NC 27599, or by email at IRB_subjects@unc.edu. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the

researchers have been notified, your specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

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 to participating in this study. 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.

Who is sponsoring this study?

This research is funded by The U.S. Environmental Protection Agency. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

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 questions, you should contact the researchers listed on the first page of this form.

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

All research on human subjects is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_ subjects@unc.edu.

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Principle investigator: Martha Sue Carraway, MD

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored with the identifying code(s).

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent