

TO:

RE: Your appointment at the EPA Human Studies Facility

STUDY: "KINGCON" Pre-screening Visit

DATE:

TIME:

SPECIAL NOTICE

If you are a UNC Student or are UNC staff or faculty:
you MUST print this appointment slip and display it on the dashboard in your car.

If you do not display it, you will be ticketed.

[Current parking information provided here.]

May be folded here for display

KINGCON Guidelines for Pre-screening Visit

Please DO NOT EAT OR DRINK ANYTHING for 8 hours prior to your screening visit.
Water is okay.

No illness or active allergies. If you are sick or have been sick or injured in the last 4 weeks, please call EPA Recruitment at 966-0604 or 888-279-9353. This includes sore throats, coughs, colds, and cold sores.

If you are unable to keep your appointment, please call Recruitment.

Thank You!
Westat EPA Recruiting

APPROVED - TRR, INC-CH
APR 23 2009

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KINGCON INSTRUCTIONS

For All Study Visits (No Bronchoscopy)

Illness. If you are sick or have been sick or injured in the last 6 weeks, please call Recruitment at 966-0604 or 888-279-9353. This includes sore throats, coughs, colds, and cold sores.

No active allergies. If you have questions about allergies, please call the EPA medical station at 966-6232.

Medications

- No over the counter pain medication for 7 days prior to all visits (Tylenol is ok)
- No vitamins C or E (or multi-vitamins containing C or E) for 7 days prior to all visits
- No antihistamines for 1 week prior to exposure
- If you require the use of a rescue inhaler (such as albuterol) within 6 hours prior to any visit, notify the medical station at 966-6232.

Smoke, Alcohol and Caffeine

- Avoid smoke and fumes for 24 hours before all visits
- Avoid drinking alcohol for 24 hours before all visits
- No caffeine for 12 hours before all study visits

Food

- On the Exposure Day eat a light breakfast and bring your lunch. You will be reimbursed \$5.00 for lunch.

Clothing and Exercise.

- Please wear comfortable clothing and shoes
- Avoid strenuous exercise for 24 hours prior to and after all visits

If you are unable to keep your appointment, please call Recruitment. Please be on time!

Thank You! Westat EPA Support Services

APPROVED FOR UNC-CH

APR 23 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

[Date]

Dear Household Member:

The U.S. Environmental Protection Agency (EPA) needs volunteers for an important research study. We hope to learn whether older adults with asthma and with a specific type of gene are more susceptible to air pollution. Your participation will help us understand how aging affects our responses to pollution. Research studies like this one have helped EPA to create national air quality standards that protect the health of all Americans.

We're recruiting non-smokers between the ages of 45 and 65 who have mild asthma and live within 50 miles of EPA's Human Studies lab in Chapel Hill, NC. We'll first ask you to come in to review your medical history, have a physical examination, pulmonary function studies, and we will collect blood samples. You can complete these examinations in two visits to the EPA, or one longer visit if that works best with your schedule. If we find that you don't qualify for the study, we'll pay you up to \$80 for your time. If you do qualify, we'll explain the study and ask you to come back for exposure to clean air and to air particles from the Chapel Hill area at two different times. The amount of air particles you'll breathe in is less than what you'd inhale on a smoggy day in an urban area.

On the day following each exposure session, we would like to perform a bronchoscopy to look into the airways of your lungs to see if the particles you inhaled had any effect on your lungs. During this exam, we'll give you a local anesthetic and insert a thin flexible tube through your nose. The anesthetic will help us make sure that you're comfortable. These exams are usually very safe. We've done more than 1,000 of them over the past 15 years. It is possible to participate in the study without having the bronchoscopy performed. If you complete all visits and procedures for the study, you'll receive up to \$1,722, and without the bronchoscopy, up to \$952.

We'll also give you breathing tests, take more blood, monitor your heart rate, and ask you to wear a heart monitor overnight. We'll give you the results of all the tests we do.

To qualify for the study, you must have mild asthma, be a non-smoker, and otherwise be very healthy. You must agree not to take any over-the-counter medicines and vitamins for 7 days before each visit.

Please call 919-966-0604 or 1-888-279-9353 to find out more about how you can volunteer.

Sincerely,

Martha Sue Carraway, MD
Principal Investigator
Human Studies Division
U.S. Environmental Protection Agency

APPROVED - IRB, UNC-CH
APR 23 2009

Recruitment Script

KINGCON: Elder Asthma Study

Title: Mechanisms by which air pollution particles exacerbate asthma in older adult mild asthmatics.

Purpose:

The purpose of this research study is to learn about whether older adults with asthma respond differently to air pollution than younger asthmatics. This is a companion study to a current EPA study of the effects of air pollution particles on young asthmatics. Researchers expect a comparison of these two studies will determine if older people with asthma are more susceptible to air pollution than are younger asthmatics. This study will also help to determine if individuals with a specific genotype are also more susceptible to air pollution. Volunteers must be healthy, non-smokers between the ages of 45 and 65 with mild, well-controlled asthma.

Procedures:

Following genotyping and medical screening, volunteers will complete a training session and two exposure and follow-up sessions. One exposure will be to clean air and one to concentrated Chapel Hill air particles. The amount of particles you will be exposed to is less than what you would likely encounter on a smoggy day in an urban area. You will breathe through a facemask during the two hour air and air pollution exposure sessions. The mask is connected to the incoming air by a short segment of hollow tubing. This set-up will limit your ability to turn your head, and your head will remain in a relatively fixed position during the two hour exposure. On the day following each exposure, a bronchoscopy procedure will be performed if you are willing and if you qualify (see CRU Bronchoscopy script, IRB #91-0679, to describe). Exposure sessions are separated by at least two weeks. Total time commitment after screening is 5 visits over about 22 hours.

Screening will require one visit to have blood drawn for which you will be paid \$30. If after screening it is determined that your specific genotype is not needed, your participation will end. If you do qualify to continue, you will be asked to complete a medical history form and then be scheduled for physical exams. Following successful completion of the physicals you will be scheduled for the training day and two exposure and follow up sessions. Study procedures will include blood sampling, breathing tests, and bronchoscopy for those who qualify. The study also will require wearing a heart monitor overnight between each exposure and follow up day.

Payment: Compensation for this study is up to \$1722 including screening depending on whether you participate in or qualify for all study procedures. Without bronchoscopy, the compensation is up to \$952.

Schedule: Genotyping (fasting blood draw), 1 visit as available
EPA medical screening (IRB #95-0518), 2 visits as available
Training (Day 1) 2 hours, at least 3 days prior to Exposure [Days and times TBD]
Day 2: Exposure: 6 hours [8 AM, Days TBD]
Day 3: Bronchoscopy follow up: 4 hours [8 AM the day after exposure]- approximately 2 hours without bronchoscopy.

Following our phone conversation today I will provide the EPA nurses with some general information about your health and specifically about your asthma. If they have additional questions, you may receive a phone call from one of the nurses in the next 2 to 3 business days.

Study Restrictions:

In addition to meeting all study eligibility criteria, volunteers must be willing to adhere to the following restrictions:

- No upper respiratory or acute illness for 6 weeks prior to exposure
- No over the counter pain medication for 7 days prior to all visits (Tylenol is ok)
- No vitamins C or E (or multivitamins w/ C or E) for 7 days prior to all visits
- No antihistamines or active allergies for 1 week prior to exposure sessions
- Avoid smoke and fumes for 24 hours before all visits
- Avoid drinking alcohol for 24 hours before all visits
- Avoid strenuous exercise for 24 hours prior to and after all visits
- No caffeine for 12 hours before all study visits
- For bronchoscopy –

Must be able to avoid aspirin for 7 days before procedure

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APR 23 2009

EX.2

Recruitment Script

No inhaled bronchodilators for 12 hours prior to bronchoscopy
Do not eat or drink anything after midnight on the evening of the Exposure Day
Must remain in the local area for 24 hours following bronchoscopy

EX. 2
