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3/11/77

Dave,

this is a new consent form for the lung function experiments. Please replace the old one with this one.

Paul Meyers.

REPOSITORY LLNL B361RmB940A

COLLECTION Institutional Review Board

BOX No. IRB Protocol File

FOLDER Active Grants-Collaborative

UNIVERSITY OF WASHINGTON OZONE
Effect on Overall Lung Function

2004814

UNIVERSITY OF WASHINGTON

& UNIVERSITY OF CALIFORNIA, LAWRENCE LIVERMORE LABORATORY

CONSENT FORM FOR INHALATION OF OZONE AND SPECIFIC RADIOACTIVE GASES FOR RESEARCH

Ozone Effects on Overall and Regional Lung Function

Principal Investigator:	Robert Frank, M.D.	Department of Environmental Health University of Washington	(206)543-4383
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The purpose of this study is to test the effect of ozone, an important air pollutant, on the pulmonary (lung) function of normal, healthy humans.

Persons who have chronic heart disease, lung disease including asthma, or have had any respiratory infection during the past six weeks may not participate. Pregnant women may not participate.

Procedure: The study will involve breathing low concentrations of ozone for two hours. The subject will sit in a small chamber shaped somewhat like a telephone booth and breathe through a mouthpiece. Before the subject enters the chamber, a narrow tube (catheter) will be passed through the nose into the rear of the throat. The subject will then swallow the catheter until the tip lies just above the stomach. A noseclip will be used to hold the catheter in place and to prevent nose breathing. The catheter is necessary to estimate intrapleural pressure (the pressure in the space between the lungs and the chest wall) which is used to calculate flow resistance (a measure of the effort required to move air through the airways). Flow resistance will also be measured by a non-invasive method using pressure waves created by a pump (forced pressure oscillatory method). The flow resistance measures require only quiet breathing on the part of the subject. Other measurements will require such simple maneuvers as inhaling and exhaling maximally, exhaling at a given flow rate and occasional breath holding or panting. In order to obtain the radioactive measurements the subject will inhale a single breath of gas tagged with a low level of radioactivity ($^{13}N_2$ or $C^{15}O_2$, both positron emitters) and hold his/her breath for 15 to 20 seconds. Following the breathing of the pollutant the subject will come out of the chamber for one hour and thereafter re-enter for another set of measurements lasting 10-15 minutes. The total length of the procedure will be 4-5 hours. Some subject will be asked to exercise moderately on a treadmill for 10-15 minutes while breathing the pollutant.

The risks involved in the study are thought to be negligible. Discomforts that may arise are as follows: nasal irritation may be felt when the catheter is first passed; the nose clip may occasionally feel tight; sitting in the chamber may be tedious. The ozone may cause burning of the throat and chest, or cough, and rarely, difficulty in breathing. Should the symptoms occur, they are likely to be slight and to disappear within minutes or hours. The total radiation exposure for the complete experiment (12 radioactive tests) will be approximately 30 mrad to the lungs, the acceptable dose limit to the lungs is 500 mrad per year. A normal chest x-ray will result in approximately 200 mrad to the skin.

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If the subject experiences excessive symptoms the experiment will be terminated. A doctor will be present throughout the experiment and thereafter will question the subject at least once daily until all symptoms are gone.

The subjects retain the right to withdraw from the study at any point. The subject will be paid $50 per two-hour exposure session. There are no personal benefits deriving from participation in the study. The rights to withdraw from the test at any time and to withhold information from non-medical persons without additional consent are protected. The subject's welfare is protected by the presence of the physician before and during the test, and by the availability of emergency hospital treatment if the need arises. The subject's identity and all information about him or her are to remain confidential.

Signature of investigator _____ Date _____

Subject's statement

I voluntarily consent to participate in this study. I have had an opportunity to ask questions.

Signature of subject _____ Date _____

COPIES: Subject
File

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