Attachment E

Form Approved
OMB No. 0920-xxxx
Exp. Date xx/xx/20xx

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Umicore Thin Film Products, Providence, Rhode Island

I. You are being asked to participate in a research study of respiratory illness at the Umicore Thin Film Products plant. The purpose of this evaluation is to determine if there is respiratory illness related to exposures at this plant.

II. The study will include the following:

A. Questions about your respiratory symptoms, work history, and health history. These questions will take about 20 minutes.

B. Blood draw: You will be asked to provide a blood sample from your arm. We will draw a total of 20 milliliters, or about 4 teaspoons, of blood for 8 different tests. We will measure indium and tin concentrations and the levels of markers of lung disease in your blood. The blood draw may cause mild discomfort, swelling, bruising, and rarely fainting. The blood draw will take about 5 minutes.

If you agree, we will draw another 10 milliliters, or about 2 teaspoons, of blood that we will store frozen at NIOSH. We will use the stored blood to repeat the measurements of the tests listed above or conduct other tests related to indium-tin oxide exposure. If the stored blood is not used, it will be destroyed when NIOSH's research on indium-related lung disease is completed.

C. Lung function test (spirometry): You will be asked to breathe in as deeply as you can and then forcefully blow out as quickly and completely as possible through a tube that you place in your mouth. You will be asked to do this 3 to 8 times. This test may be tiring, and you may feel momentary lightheadedness or chest discomfort. If, at any time, you feel unable to continue, the test will be terminated. This test takes about 10 minutes.

D. Diffusing capacity test: You will be asked to breathe in a harmless gas mixture containing helium and a very small amount of carbon monoxide, then hold your breath for 10 seconds and then breathe out. This will be repeated 2 or 3 times to measure how well your lungs transfer oxygen. You may feel momentary lightheadedness. This test takes about 20 minutes.

E. Lung volume test: You will be asked to breathe 100% oxygen through a tube for several minutes. We will measure the amount of nitrogen in the air you breathe out during the test. You may experience a feeling of dryness in your mouth during inhalation. This test takes about 10 minutes.

F. Exhaled nitric oxide test: We will ask you to take a deep breath through a special mouthpiece, and then breathe out steadily for 10 seconds. We will measure the amount of nitric oxide in the air you breathe out. You may feel momentary lightheadedness. This test takes about 10 minutes.

G. High resolution computed tomography (HRCT) scan of the chest: This is an X-ray test. You will be requested to wear a gown and remove metallic objects such as jewelry. You will be asked to lie down on the scanner table. You will be asked to take a deep breath and hold it and then blow out. The test will take about 15 minutes.

This X-ray test exposes you to radiation. Radiation is a risk factor for cancer. The risk of cancer is related to radiation dose. The radiation dose you will receive during the scan is between 0.4 and 1 millisieverts (mSv). For comparison, the radiation dose associated with a standard chest X-ray is about one-fifth as much. The average natural background radiation dose from sources in the environment is between 2 and 3 mSv per year. Thus, the radiation dose of the scan used in this study is equivalent to about 2 to 6 months of natural background radiation.

If you are a woman and are pregnant or may be pregnant, you will not be allowed to have the HRCT scan, due to the potential risks of radiation to the fetus.

All together, your participation should take about 90 minutes, plus the additional time spent traveling and waiting for your tests. Transportation between the radiology center where you will have the HRCT scan of the chest (Rhode Island Medical Imaging, One Randall Square, Providence, Rhode Island) and Umicore Thin Films Products will be provided to you at no charge. Transportation will be by taxi service. You do not need to make any arrangements for the HRCT scan or the transportation to the radiology center.

III. The benefits to you from participating include the free medical tests. NIOSH will provide you and your doctor (if you wish) with the results of your medical tests. You may also elect to have NIOSH provide the results of your medical tests to the physician conducting medical surveillance for Umicore. Due to the time it takes to analyze the blood samples in the laboratory, you may receive the results of the blood tests later than the results of the other medical tests. The overall study summary (without names or other personal identifying information) will be provided to Umicore and the project's employee representative. If you ask, NIOSH will send you a copy of the final report. One disadvantage, besides the slight discomfort and inconvenience described above, is that a test result may be outside the range of "normal" even though nothing is wrong. This could result in further medical evaluation that may not have been necessary.

IV. 1These procedures are standard medical tests, except for the blood tests. For all but the HRCT scan, there are no alternative procedures. An alternative to the HRCT scan is standard chest X-ray. However, studies in Japan have found that standard chest X-ray is much less sensitive for indium-related lung changes than HRCT scans.

V. Injury from participation is unlikely. However, if injury results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: General Law Division of OGC, request the Claims Office: (202) 233-0233. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the Federal government. If an injury or harm should occur to you as the result of your participation, you should contact Kristin Cummings, MD, MPH at (800) 232-2114 or the current chair of the NIOSH Human Subjects Review Board, Mark Toraason, (513) 533-8591.

VI. If you have any reaction to the tests or procedures, you should contact Kristin Cummings, MD, MPH at (800) 232-2114. You should also Dr. Cummings if you have any questions concerning this study or your participation. If you have questions about your rights as a member of this study, contact Mark Toraason, Chair, NIOSH Human Subjects Review Board, (513) 533-8591.

VII. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

Your participation will take place during normal work hours on company time. You will not be compensated by NIOSH for participation, nor will you be charged for any of the medical tests.

VIII. Use of Information

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information

we are collecting is maintained and retrieved by personal identifiers, such as your name and birthdate, it will become part of the CDC record system (Privacy Act system 09-20-0147, "Occupational Health Epidemiological Studies") and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed below.

The Information you provide may be disclosed to:

- Appropriate state or local health departments to report communicable diseases;
- A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;
- Private contractors assisting NIOSH;
- Collaborating researchers under certain circumstances to conduct further investigations;
- One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;
- The Department of Justice or the Department of Labor in the event of litigation;
- Congressional offices assisting an individual in locating his or her records;

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

The relatively small number of participants precludes the development of a public use dataset, as confidentiality could not be assured.

IX. SIGNATURES

I have read this consent form and I agree to participate in this study.

Please initial below if you agree to these additional conditions:

I agree_____ to have 10 milliliters of blood drawn and stored as detailed in the consent form.

PARTICIPANT NAME _____ Age _____ Date _____
(print)

_____
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ Date _____
(signature)