

Appendix G1: Consent Form (English)

**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

- I. You are being asked to participate in a research study of respiratory illness among microwave popcorn and flavoring workers. The purpose of this study is to investigate the spectrum of lung disease occurring among flavoring-exposed workers.

- II. The study will include the following:
 - A. Questionnaire: This will include questions about respiratory symptoms, work history, and health history. The questionnaire will be given by a NIOSH representative. This will take approximately 20 minutes.

 - B. Spirometry (breathing test): 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 at least 3 times, and possibly several more 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.

 - C. Bronchodilator test: Depending on the results of your spirometry test, you may be asked to inhale 4 puffs of a medicine that will open your airways if they are at all narrowed. After you have received this medication, you will be asked to blow in the spirometer again to see if your airways have responded. This medicine may make your heart beat fast or make you feel jittery for about 30 minutes. This test takes about 20 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, 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. Total lung capacity: You will be asked to breathe oxygen that contains a tracer gas (nitrogen) through a tube. Then you will be asked to breathe regular air while the tracer gas (nitrogen) you breathe out is measured. You may experience a feeling of dryness in your mouth during inhalation. This test takes about 10 minutes.
- F. High-resolution computed tomography (HRCT) 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 then 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 3 and 4 millisieverts (mSv). For comparison, the radiation dose associated with chest X-ray is 0.1 to 0.2 mSv, and the natural background radiation dose from sources in the environment is between 2 and 3 mSv per year.

- G. Blood draw: You will be asked to provide a blood sample from a vein in your arm. We will draw 30 milliliters, or about six teaspoons, of blood that we will store frozen at NIOSH. The blood draw may cause mild discomfort, local swelling, and bruising at the blood draw site, and rarely fainting. The blood draw will take about 5 minutes. We may use this blood in the future for tests related to flavoring-related lung disease risk only. Some tests may reflect inflammation in the lungs. Other tests may be developed to see if you have genes related to how your body processes flavoring chemicals. If you give permission, this sample will be stored with a unique number so that we know it is yours and can link it with your other information. Once we know the specific blood tests we will be using in this study, we will contact you to describe the tests and ask for your written permission to perform the tests on your blood sample. We will also ask you at that time if you would like to receive a written copy of your blood test results. We will store this sample until the end of 2020 at which time the blood will be destroyed.
- H. If you are pregnant or may be pregnant, you will not be allowed to have the HRCT scan (section F) due to the potential risks of

radiation to the fetus. Although the diffusing capacity test (section D) is not specifically prohibited for pregnant women, out of an abundance of caution, we will not administer this test to women who are pregnant or may be pregnant.

- III. Altogether, your participation in this study will take approximately 3 to 3.5 hours, which includes the time spent traveling and waiting for your tests. Transportation to and from the HRCT facility is free and will be by taxi service. You do not need to make any arrangements for the HRCT scan or the transportation to the radiology center.
- IV. 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 breathing tests and HRCT scan. 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.
- V. These procedures are standard medical procedures (except for the possible blood tests as described above). For all but the HRCT scan, there are no alternative procedures. An alternative to the HRCT scan is a standard chest X-ray. However, HRCT scans have been found to be more effective in detecting lung disease than standard chest X-rays.
- VI. 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 Claims Office: (201) 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 Rachel L. Bailey, DO, MPH, at (800) 232-2114 or Mark Toraason, PhD, (513) 533-8591, the chair of the NIOSH Institutional Review Board.
- VII. If you have any reaction to the tests or procedures, you should contact Jean Cox-Ganser, PhD or Rachel Bailey, DO, at (800) 232-2114. You should also call Dr. Bailey if you have any questions concerning this study or your participation. If you have questions about your rights as a member of this research study, contact Mark Toraason, PhD, (513) 533-8591.
- VIII. 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.

For your participation in one or more parts of the research study, you will receive a gift card to a local merchant for \$50. Gift cards will be given at the completion of medical testing.

IX. 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, it will become part of the CDC record system 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 in Appendix A (the Privacy Act).

X. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this study.

PARTICIPANT NAME _____ Age _____
(print)

(signature) Date _____

I agree to have my blood drawn for the purposes described above.

PARTICIPANT NAME _____ Age _____
(print)

(signature) Date _____

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

REPRESENTATIVE NAME _____

(print)

Date _____

(signature)

cc

Participant

Appendix A for Consent of Medical Testing

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, “Occupational Health Epidemiological Studies and EEOICPA Program Records” and 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.