



Long-term Re

posed Workers

You are being asked if you would like to volunteer for a research study. This document gives you information about the study. A member of the research team will review this study with you. They will answer all your questions. Please read the information below. Ask questions about anything you do not understand before deciding if you want to volunteer.

- **Key Information:** This study will be done to help the National Institute for Occupational Safety and Health (NIOSH) understand the long-term respiratory health effects among styrene-exposed workers and help develop effective prevention strategies for future styrene-exposed workers. This study will be done once at **XXX in Bellingham/Kelso**, WA and will take about 2.5 hours. During this research project, we will have you complete a medical and work history questionnaire, breathe into some machines to evaluate lung function, provide a blood sample, and perform a color vision test. Some participants may feel lightheaded, dizzy, weak, or have chest discomfort with the lung function tests. The blood draw may cause mild discomfort, local swelling, and bruising at the blood draw site. The NIOSH technicians will always take steps to minimize any discomfort or risk caused by any medical test. You will be well-informed of any benefits and risks associated with participation in the study. This study is completely voluntary. You may choose to be in this study or not. You may answer some or all questions asked, and you may finish some or all the study procedures offered. You may drop out of the study at any time, for any reason without penalty or loss of benefit to which you are otherwise entitled. Some individuals may not choose to participate due to the inconvenience of having to travel to medical survey, the time involved in participating in the medical survey, or feeling uncomfortable with providing personal medical information to the federal government.

### Who is doing the study?

The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).

### Why is NIOSH doing this study?

This study is to understand the long-term respiratory health effects among styrene-exposed workers and develop effective prevention strategies.

### What is required for me to participate?

In order to join this study, you must have worked 1 or more days at either the Uniflite or Tollycraft boatbuilding plants during January 1, 1959 through September 30, 1978. You must also review and sign this informed consent form.

### What will I be asked to do?

- **Questionnaire:**
  - We will ask you questions about your health, certain medical conditions and your work history.
  - The questionnaire should take about 45 minutes.
- **Breathing Tests:**
  - **Exhaled Nitric Oxide:** 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

## Consent to be in a Research Study

### *Long-term Respiratory Diseases Among Former Styrene-Exposed Workers*

you breathe out. This test takes about 5 minutes.

- o **Impulse Oscillometry:** We will ask you to breathe normally through a machine for 35 seconds as gentle pulses of air come through the tube. You will be asked to breath like this at least 3 times, possibly more. We will measure how your airways react to the gentle pulses. The impulse oscillometry test takes about 10 minutes.
  - o **Spirometry:** We will ask you to breathe in as deeply as possible and then forcefully blow out into a machine as quickly and completely as possible. You will be asked to breath like this at least 3 times, and possibly more, until the technician has 3 repeatable procedures. This test measures how much air you can breathe out and how fast you breathe it out. This test takes about 10 minutes.
  - o **Bronchodilator test:** Depending on the results of your spirometry test, we may ask you to inhale 4 puffs of a medicine (albuterol) that will open your airways if they are at all narrowed. The dose of albuterol is considered “off label” which means the medication is being used in a manner not specified in the FDA’s approved packaging label or insert; it is below the label approved dose and has been shown to be safe to use with this test. If you are asked to participate in this test, you will meet with the NIOSH physician to discuss the risks and ask questions about the medication. After you have received this medication, we will ask you to repeat the spirometry and oscillometry test again to see if your airways have responded. This medicine may make your heartbeat fast or make you feel jittery for about 30 minutes. This test takes about 20 minutes.
  - o **Multiple-Breath Washout:** We will ask you to breathe naturally through a machine that delivers 100% oxygen for several minutes. You will repeat the procedure 3 times. This test measures your lungs ability to exchange gases. This test takes about 30 minutes.
- **Color Vision Test:**
    - o We will ask you to put 15 caps in color order.
    - o This test screens for multiple types of color blindness.
    - o This test typically takes 5 minutes
  - **Blood Tests:**
    - o We will ask you to provide a blood sample from a vein in your arm. We will draw about 20 milliliters, or approximately 4 teaspoons, of blood.
    - o We will look at your blood for biomarkers of certain types of lung disease.
    - o The collection of blood will take about 5 minutes.

### **When, where, for how long will you need me?**

- The study will be done at XXX in Bellingham/Kelso, WA.
- The questionnaire, breathing tests, and blood test should take about 2.5 hours, which includes any time waiting between testing stations.

### **Are there any risks?**

- During the breathing tests you may feel lightheaded, dizzy, weak, have chest discomfort, or faint.
- If you are selected to take the medication to dilate parts of your lungs (i.e. albuterol), the medication may make your heartbeat fast, give you a headache, irritate your throat or nose, or make you feel jittery or dizzy for about 30 minutes. It is very rare but some people might have an allergic reaction to albuterol called a hypersensitivity reaction.
- The blood draw may cause mild discomfort, local swelling, and bruising at the blood draw site, and rarely it may cause fainting.
- Health care expenses may be added by your healthcare provider if lung function testing results

## Consent to be in a Research Study

### *Long-term Respiratory Diseases Among Former Styrene-Exposed Workers*

recommend further medical evaluation. A study procedure result may be outside the range of "normal" even though nothing is wrong. This could result in your healthcare provider recommending further medical testing that, ultimately, may not have been necessary.

- Although the risk is low, some participants may experience feelings of stress, worry, and anxiety from receiving lung function or color vision tests results outside the "normal" range.
- Unintentional disclosure of personal identifiable information collected during the medical survey.

NIOSH will take precautions to minimize potential risks. To determine if it is ok for you to participate in all the breathing tests, the NIOSH technician will ask you a series of questions about current medications, recent medical procedures, and take your blood pressure. Blood draws will be performed by an experienced phlebotomist. To minimize unintentional disclosure of personal identifiable information, all documents will be stored in a locked cabinet or on a secure server only accessible to a limited number of study investigators. All testing results or samples will be labeled with a unique ID number.

#### **Is my participation voluntary?**

This study is completely voluntary. You may choose to be in this study or not. You may answer some or all questions asked and participate in some or all of the study procedures offered. You may drop out of the study at any time, for any reason without penalty or loss of benefits to which you are otherwise entitled.

#### **What if I'm harmed?**

NIOSH will summon emergency medical aid by calling 911. A physician trained in cardiac life support and an automatic external defibrillator (AED) will always be available during the medical survey. The NIOSH physician will provide any stabilizing care until emergency medical services (EMS) arrive.

If NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of research-related injuries will be provided by NIOSH, the CDC, or the Federal Government. However, if you believe NIOSH has been negligent in conducting the research study and you believe you have suffered a harm as a result, you have the right to pursue a legal remedy under the Federal Tort Claims Act (28 U.S.C. §§ 2671-2680 and 28 U.S.C. § 1346(b)). To learn more about how to file a Federal Tort claim, call the General Law Division of the HHS Office of the General Counsel at (202) 619-2155 or go to <https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html>.

#### **Will I be reimbursed or paid?**

You will be provided a \$50 gift card for your participation in one or more parts of the research study. Gift cards will be given when you leave the medical survey.

#### **Are there benefits?**

- Although there are no direct benefits to you, current and future workers exposed to styrene may benefit from the results of this evaluation.

## **Consent to be in a Research Study**

### *Long-term Respiratory Diseases Among Former Styrene-Exposed Workers*

#### **How will I receive my results?**

At the bottom of the consent form, you will be given the option to accept or decline your lung function and color vision tests results. Because the blood tests will not have any clinical interpretation, NIOSH will not provide the blood tests results. If you choose to receive your results, we will mail the results you select to receive in a letter to the address you provide. Reviewing individual lung function testing results may take 3-4 months to be completed, so there may be a delay before you receive your results. We will present summarized lung function results to the whole cohort in Bellingham, WA and Kelso, WA once all test results have been analyzed. When this presentation has been scheduled, you will receive an invitation.

## Consent to be in a Research Study

### *Long-term Respiratory Diseases Among Former Styrene-Exposed Workers*

#### Will my personal information be kept private?

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the CDC which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

HS System of Records Notices (SORNs) are required for studies in which the Privacy Act is relevant. As required by The Privacy Act, HHS publishes SORNs to give public notice of the records it keeps. These are found by personal identifiers. Each SORN describes the types of information contained in the records, the legal right for collecting and keeping the records, and how the records are used within HHS. It also contains the purposes (referred to as "routine use") for which HHS may share the records to non-HHS parties without the participant's consent.

09-20-0147 Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records. **Categories of Individuals Covered by the System:** The segment of the population exposed to physical and/or chemical agents or other workplace hazards that may damage the human body in any way.

NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. This research study will result in identifiable information that will be placed in a locked environment on a secured NIOSH campus. Only de-identified study information will be utilized in the research data reports and publications. De-identified information could also be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or a legal representative. NIOSH may collect and keep information about you, including your results from this study, along with your personal identifiable information collected based on 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)

#### Future Research

Identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

#### Whom can I talk to if I have questions?

## Consent to be in a Research Study

### *Long-term Respiratory Diseases Among Former Styrene-Exposed Workers*

For questions about this research study, including concerns and complaints, contact the principal investigator, Suzanne Tomasi, DVM, MPH at (304) 285-6115, [yc4@cdc.gov](mailto:yc4@cdc.gov), or 1-800-232-2114.

For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board in the Human Research Protection Program at (513) 533-8591.

#### Requesting Lung Function Tests Results

- I would like to receive my lung function tests results. Please mail them to me at the following address:

---

- I do not want to receive my lung function test results.

#### Requesting Color Vision Test Results

- I would like to receive my color vision tests results. Please mail them to me at the following address:

---

- I do not want to receive my color vision test results.

#### Your signature

I was told about this study. Any questions I had were answered. I agree to be in the study.

---

Printed name of participant [*Optional*]

---

Participant signature

Date

I have accurately described this study to the participant.

---

NIOSH representative signature

Date