Form Approved
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Consent for a R[illegible] T[illegible]

Long-term Respiratory Diseases among Former Styrene-Exposed 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 Radiology Center in Bellingham/Kelso, WA and take less than 1 hour. During this research project, you will have an X-ray test called a high-resolution computed tomography (HRCT) scan of the chest. HRCT scans have been found to be more effective in identifying small airway lung diseases. The HRCT scan will help NIOSH understand the long-term health effect of styrene-exposed workers. 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 HRCT scans will be done using the lowest possible dose of radiation. 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. This study is completely voluntary. You may choose to be in this study or not. 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 radiology facility, the time involved in participating in the HRCT scan, or feeling uncomfortable with providing personal medical information to the federal government. However, this could be an opportunity for you to receive this expensive medical test for free.

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. HRCT scans have been found to be more effective in detecting lung diseases like obliterative bronchiolitis, which is a rare, irreversible lung disease defined by narrowing of the bronchioles from inflammation and fibrotic changes. The HRCT scan will help NIOSH understand the long-term health effect of styrene-exposed workers.

What is required for me to participate?

In order to join this study, you must have completed the medical survey in XXX and worked in a department at Uniflite or Tollycraft boatbuilding plants with a history of a high exposure to styrene. Additionally, you reported respiratory symptoms (coughing, shortness of breath, or wheeze) or your lung test results were outside the normal range. You must also review and sign this informed consent form.

- This is an X-ray test. We will request you to wear a gown and remove metallic objects such as jewelry. We will ask you to lie down on the scanner table. We will then ask you to take a deep breath, hold it, and then blow out. The test will take about 15 minutes.

When and where will you need me?

- This test will be done at XXX in Bellingham/Kelso, WA.
- The consent form and HRCT scan should take less than an hour, which includes any time waiting.

Are there any risks?

- 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 HRCT scans will be done using the principle to administer the lowest possible dose of radiation. 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.
- If you are pregnant or may be pregnant, you will not be allowed to have the HRCT scan because of potential risk of radiation to the unborn baby.
- A test 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.
- HRCT scans might identify abnormalities such as mass-like lesions that require further medical testing by your personal healthcare provider and cause a psychological effect.
- Unintentional disclosure of personal identifiable information collected during the HRCT scan.

NIOSH will take precautions to minimize potential risks. The HRCT scans will be done using the principle to administer the lowest possible dose of radiation. 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 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 the medical treatment staff at the XXX radiology center. 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.

Consent for a High-resolution computed tomography (HRCT) Study of the Chest

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Will I be reimbursed or paid?

We will not pay or reimburse you for taking part.

Are there other benefits?

- You will receive this medical test free of charge.
- Workers exposed to styrene may benefit from the results of this evaluation.

How will I receive my results?

At the bottom of the consent form, you will be given the option to accept or decline your HRCT scan results. If you choose to receive your results, NIOSH will provide you with the results of your HRCT scan. We will mail your results in a letter to the address you provide. If the clinical read of your HRCT scan identifies any urgent medical concerns, a NIOSH physician will contact you by phone within in 3-5 days after the scan. Otherwise, individual HRCT scan results will be mailed in 1-2 months from the date of your scan. We will present summarized lung function and HRCT scan 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.

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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.

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Whom can I talk to if I have questions?

For questions about this research study, including concerns and complaints, contact the principal investigator, Suzanne Tomasi, DVM, MPH at (304) 285-6115, yxc4@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 Results of the HRCT Scan

☐ I would like to receive my HRCT scan results. Please mail them to me at the following address:

_____

If urgent, please call me at: _____

☐ I would like to only receive my HRCT scan results if they suggest that medical follow-up is need

☐ I do not want to receive any of my HRCT scan results.

Your signature

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

_____
Printed name of participant [*Optional*]

_____
Participant signature Date

I have accurately described about this test to the participant.

_____
NIOSH representative signature Date