

Consent to Participate in Health Hazard Evaluation (HHE) Activities

HETA 2023-0000 – Name – City, State

Who is conducting this evaluation?

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).

What is the purpose of this evaluation?

This evaluation was requested by the (employer, employees, union) to assess (hazard) in (work area).

What will I be asked to do?

Questionnaire: You will fill out a questionnaire about your work history, health, and symptoms you have when working around (hazard). You will be asked to complete the questionnaire yourself, but a NIOSH representative will be present to assist you and check it for completeness (or insert - NIOSH staff will ask you questions about certain medical conditions and health symptoms you may have experienced, and your work history.) This should take about (range, e.g., 10-20 minutes).

Medical Tests (list tests- examples below):

- 1. 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 you breathe out. This test takes about 10 minutes.
- 2. Impulse Oscillometry:** We will ask you to breathe normally through a machine for 15 to 30 seconds as gentle pulses of air come through the tube. You will repeat this at least three times, possibly more. We will measure how your airways react to the gentle pulses. This test takes about 5 minutes.
- 3. 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 repeat this at least 3 times, and possibly more. This test measures how much air you can breathe out and how fast you breathe it out. This test takes about 10 minutes.

You will do breathing tests to assess your lung function. You will be asked to breathe in as deeply as you can and 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 (three) times, and possibly more times. The test typically takes (range) minutes.

Is my participation voluntary?

You may choose to be in this HHE or not. You may answer some or all questions asked and participate in some or all of the medical tests offered. You may drop out of the evaluation at any time, for any reason and with no penalty. However, your participation will help NIOSH better understand the health effects experienced by workers.

Where and when is the evaluation?

The questionnaire and medical tests will take place at (location) during your work shift. Altogether, your participation should take about (range) minutes, which includes time completing this consent form, filling out the questionnaire, taking the medical tests and waiting between the questionnaire and medical tests.

Will I be reimbursed or paid?

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to - CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333 ATTN: PRA (0920-0953).

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NIOSH will not pay or reimburse you for participating in this evaluation.

What if I'm harmed?

*This paragraph is **mandatory** for all NIOSH consent forms. **Do not change or remove it.***

NIOSH will summon emergency medical aid by calling 911 if needed. NIOSH will not provide payment for medical care or compensation. If you believe NIOSH has been negligent in conducting the evaluation 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>.

Are there any risks?

The breathing 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 stopped.

A test result may be outside the range of "normal" even though nothing is wrong. This could result in a recommendation for further medical evaluation. You can discuss with your doctor whether further medical evaluation makes sense for your situation before deciding to follow the recommendation.

There is a slight risk that the information we collect about you could be accidentally disclosed to someone else. We will minimize this risk by identifying your information by code only and by only releasing summaries of data from all participants to your employer or in publications.

Are there any benefits?

You will receive these medical tests free of charge, and NIOSH will provide you and your doctor (if you wish) with all findings from your medical tests. You, your co-workers, and others may benefit from the results of this evaluation by learning more about potential exposures at the workplace.

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Will my personal information be kept private?

NIOSH will protect your personal information to the extent allowed by law. NIOSH is allowed to collect and keep information about workers, including your results from this HHE, 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 HHE. You are free to choose not to be in this HHE. It is up to you.

You should know that there are conditions under the Privacy Act where your information may be released such as:

- Appropriate state or local health departments to report communicable diseases;
- 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. Your personal identifiable information (PII) will be kept in locked storage containers while at the workplace and we identify your samples and data collection forms by code only, when possible. The documents containing PII will be stored at secure NIOSH facilities and, if needed, stored on NIOSH internal computer systems that are only accessible to authorized NIOSH staff according to federal recordkeeping policy. We will release summaries of data from all participants with no individual results to your employer or in publications.

Will my personal information or information collected from me be used in other studies?

We will not use your information that we collect in future HHEs or share your information. Data sent back to the company in summary form or published in the final report may be used in future NIOSH studies.

Will I or anyone else receive my results?

NIOSH will mail you and your doctor (if you wish) your medical test results. Your results will not be shared with your employer. The employer will receive a summary of results from all participants, but individuals will not be identified in the summary.

The report for this HHE will include a summary of all results. The report will be posted on the NIOSH web site.

Who can I talk to if I have questions?

For questions about this evaluation, contact (name of project officer) at (e-mail address) or (telephone number).

If you have any comments about the tests or procedures, you should contact (name, title, and phone of Medical Officer).

For questions about your rights, your privacy, or harm to you, please contact the Associate Director for Science, at (###) ###-####.

Your signature

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

Participant signature _____ Date _____

Printed name _____ Age _____
Would you like to receive a copy of your results (Circle One): Yes No

Please send to me electronically at (email address): _____

Please send me a printed copy at (mailing address): _____

If you want your results shared with your medical provider, please provide their contact information here:

Medical Provider Name: _____

Address: _____

Telephone Number: _____ Fax Number: _____

Would you like to receive a copy of the final report (Circle One): Yes No

Please send to me electronically at (email address): Check here to use same email address as above

Please send me a printed copy at (mailing address): Check here to use same mailing address as above

NIOSH Representative Signature

I have accurately described this evaluation to the participant.

NIOSH representative signature _____ Date _____