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**Centers for Disease Control
 and Prevention**
 National Institute for Occupational
 Safety and Health

<p>Consent to be in a Research Study</p> <p><i>Noise Exposures and Hearing Loss in the Oil and Gas Extraction (OGE) Industry</i></p>	
<p>1</p>	<p>Key Information Summary</p> <p>Study Information:</p> <p>This is a research study that asks the following questions:</p> <ul style="list-style-type: none"> • What are the levels of workplace noise and chemicals that may impact hearing? • How many oil and gas workers in the study experience these exposures and hearing loss? <p>This study is relevant to you because noise and chemicals may be impacting your health. Hearing loss can damage your ability to communicate or listen to music. Hearing loss can increase your risk of depression and heart problems too.</p> <p>During this study, we may ask you for information such as your name, job title, age, work activities performed, past and current hearing loss symptoms, and mailing and email addresses.</p> <p>Participation in the Research Study:</p> <ul style="list-style-type: none"> • We invite you to participate in this research study. You do not have to participate if you do not want to. • About one hundred workers will participate in this study. • If you participate, we will ask you to answer questions about your hearing. We will also ask you about your experiences that may have impacted your hearing, like noise. It should take you less than 20 minutes to answer the questions. • We may also ask you to wear devices that measure noise and

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chemicals. We might ask you to wear the devices for three to four days. We would also observe your normal work activities and practices.

- We may also ask you to take a hearing test (audiometric exam) that will take about 20 minutes.

Here are some reasons you may not want to participate:

- You may have feelings of distress if you learn you have hearing loss or have been exposed to high levels of noise or chemicals.
- We will do what we can to keep your personal information secure, but there is a possibility your personal information might be released.
- You may experience some minor discomfort from wearing the devices we use to measure chemicals in the air.
- While the COVID-19 pandemic is ongoing, there is an additional small risk of being exposed to a NIOSH researcher who has COVID-19 while participating in this study and possibly getting sick yourself. However, this risk is greatly reduced since NIOSH researchers are using a layered approach of strategies to minimize your risk of exposure to COVID-19 and maximize your protection against infection. This includes researchers being vaccinated or having taken a screening test, limiting the amount of time for in person interaction and masking during those interactions. Also, most people who are infected with the virus that causes COVID-19 do not experience severe illness.

Here are benefits and reasons you may want to participate:

- Workers may benefit from improved recommendations from NIOSH to protect worker health and safety in the industry. If you wear the devices to measure noise and chemicals, you can learn how much noise and chemicals you experience while at work.
- If you participate in a hearing test, you can learn how well you hear. You could use this information to get help with your hearing.

Findings from this study will help us understand noise and hearing loss during oil and gas extraction activities. We will also better understand ways to reduce and control these exposures. A final summary report will be sent to the company. Your name will not be included in this report. We ask that each company post this report in an area visible to the study participants and other workers at the company.

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2	Who is conducting 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).
3	What is the purpose?	This study will help oil and gas companies protect workers' hearing. The study may lead to changes in equipment, work practices, or personal protective equipment (PPE).
4	What will I do?	<p>As a participant you will be asked to fill out a questionnaire to tell us about noise and chemical exposures you have, identify work locations and activities you think are noisy, and tell us if you have trouble hearing.</p> <ul style="list-style-type: none">• You may also be asked to wear one or two sampling equipment. One is a small monitor (weighing 3 ounces) clipped to your collar that measures noise levels. One is a pump (weighing less than 2 pounds) attached to your belt. The pump has tubing clipped to your collar during your shift and takes an air sample. These samples will be sent to a lab to measure hexane, toluene, xylene, ethylbenzene, and propyl benzene in the air near you during your workday. Wearing the equipment should cause minimal physical discomfort or harm, if any. You will wear this equipment during your entire shift for each of 3-4 consecutive days while you do your normal work activities.• Have your hands wiped with wet wipes if working with lead-containing pipe-dope.• Allow us to watch you work. NIOSH researchers will make observations during the work shift and may take notes about tasks throughout your workday. <p>You may also be asked to:</p> <ul style="list-style-type: none">• Complete a hearing test called an audiometric exam. This includes sitting in a sound-proof booth with headphones on to listen and respond to a series of sounds at different volumes. This allows us to identify hearing loss. You will receive your hearing test results at the end of the test if you want them. <p>As part of studying exposures during certain activities, photos may be collected of workers performing work activities. Before taking photos of you, we will ask you to give us permission to use photos using a release</p>

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		<p>form, which is different from this consent form. Photos will only be taken of you if you have given permission and signed a release form. Photos will be used to show typical work activities. These may be included in reports to the company or other products NIOSH produces. Photos will not include any individuals other than workers being observed.</p> <p>A participant number will be attached to your data. Only the NIOSH research team will have the link between your name and this number. Your contact information will only be used to reach you about the study and to provide you with your individual exposure results if you want them.</p>
5	When, where, for how long will I be needed?	<p>Researchers from NIOSH will come to your worksite or employer-selected location. Researchers will ask workers to complete a questionnaire. The questionnaire should take approximately 20 minutes to complete. Researchers will measure your exposures to noise and chemicals with monitors. Researchers will be onsite for three to four days. If you participate in the measurements, we will attach one or two pieces of sampling equipment to you at the beginning of the shift. This will take about five minutes. We may ask you to allow us to check the sampling equipment periodically during the day. At the end of the shift, we will remove the devices, which will also take about five minutes.</p> <p>If hearing tests are being offered at your worksite and you choose to participate, you will be needed for approximately 20 minutes. These will be conducted in a NIOSH mobile unit at your worksite or other employer-selected location.</p>
6	Are there any risks?	<p>Injury or harm from this project is unlikely.</p> <ul style="list-style-type: none"> • If you participate in a hearing test, you may learn you have hearing loss, which you may find distressing. • You may learn from the study measurements that you were exposed to excessive levels of noise or chemicals, which you may find distressing. • If you wear any noise or chemical measurement devices, you may experience a low level of discomfort. Researchers will use the lightest devices possible for data collection. They will adjust the devices so that you find them as comfortable as possible. You can tell the researchers if

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		<p>you feel any discomfort and they will adjust or remove the equipment.</p> <ul style="list-style-type: none">• We do not have any reason to think that the noise or chemical measurement devices you might wear are dangerous.• There is a very low risk that information we collect about you could be accidentally disclosed to someone else. If this were to happen, you may experience psychological or social stress due to your loss of privacy. We will minimize this risk as much as we can. We will only use your name or age when absolutely necessary. Your name or age will <u>not</u> be attached to the noise measurements, chemical measurements, or answers to the questions you complete. We will use a study number instead. We will not share your name, your study number, or any of the answers you provide with your employer. When we share our study results, we will only share summaries of the data. For example, we might say “10 workers at this location had high noise measurements”.• NIOSH will pay for the hearing exam that may be performed as a part of this study. If you decide to seek further medical evaluation or treatment, you will be responsible for those costs.• The study activities may involve risks to you that are currently unforeseeable. <p>If researchers find a very dangerous situation at your work site, they will immediately notify the workers and management at your company. If researchers see behaviors or conditions that are not immediately dangerous but could be improved, they will inform the workers and management at closeout meeting at the end of the site visit. At this meeting, researchers may also share their observations, including observations of PPE use and controls. Researchers will provide preliminary recommendations to reduce potential exposures, without identifying individual workers.</p>
7	Are there any risks related to exposure to COVID-19 during	<p>COVID-19 is a disease caused by a virus called SARS-CoV-2. COVID-19 most often causes respiratory symptoms that can feel much like a common cold, the flu, or pneumonia. Most people with COVID-19 have mild symptoms and some may have no symptoms, but some people can become severely ill, including hospitalization or even death.</p> <p>COVID-19 spreads when an infected person breathes out small droplets and</p>

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participation in this study?

particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. There is a very small risk you could get COVID-19 through an in-person interaction while participating in this study. To minimize your risk of exposure to COVID-19 and maximize your protection against infection, NIOSH researchers may take several extra precautions, including:

- staying up to date with COVID-19 vaccines or screening negative for infection by testing.
- limiting the amount of time spent closely interacting with you.
- wearing masks.

Most people who are infected with the virus that causes COVID-19 do not experience severe illness. However, some people may be at increased risk such as older adults (the risk increases with advancing age, especially above 50); pregnant people; persons with a variety of underlying medical conditions, and persons not up to date with COVID-19 vaccines. Serious illness from COVID-19 could result in healthcare expenses to you and could potentially result in temporary loss of income due to missed work time. Illness resulting from COVID-19 could also result in hospitalization, long term sickness, disability, death, and/or psychological effects that are currently uncertain or unknown. If you want to learn more about persons who may be at increased risk of severe illness from COVID-19, please visit CDC's webpage: 'People with Certain Medical Conditions' (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>).

If a researcher learns he or she has COVID-19 within 48 hours of close contact with you or your co-workers, we will notify you and your company and provide information on testing and treatment. If you learn you have COVID-19 within 48 hours of participating in the study, please notify the primary investigator to be able to inform research team members to follow CDC requirements.

Symptoms of COVID-19 are listed on the CDC website. Please contact your medical provider if you are experiencing symptoms that are concerning to you.

COVID-19 Close Contact Notification:

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		<p>In the event I am considered a close contact of a NIOSH research team member who develops symptoms of COVID-19 within 48 hours of interacting with me and subsequently tests positive for COVID-19, I will be contacted by a NIOSH research team member at the phone number listed below.</p> <p><input type="checkbox"/> No, please do not contact me. <input type="checkbox"/> Yes, please notify me.</p> <hr/> <p>Printed name of participant</p> <hr/> <p>Participant signature Date</p> <hr/> <p>Participant phone number (Mobile, home, other)</p> <p>OK to leave voicemail: <input type="checkbox"/> yes <input type="checkbox"/> no</p>
8	Are there other benefits?	<p>By participating in this study, you will help companies in the oil and gas industry protect the hearing ability of oil and gas workers.</p> <p>You may have the chance to learn about levels of noise and chemicals in your workplace.</p> <p>You may have the chance to learn about your hearing ability at no cost to you. If you learn that you have hearing loss, that information can help you protect your hearing.</p>
9	Is my participation voluntary?	<p>You are invited to participate in this study, but you do not have to participate. Even if you choose to participate, you do not have to participate in every part of the study or answer every question. You may stop participating at any time, for any reason. Your decision to participate or stop participating will not result in <u>any</u> penalty to you. Information you provide prior to stopping participation will be maintained in accordance with data privacy practices and included in analysis unless you request to exclude that data. A request to withdraw from the study can be done verbally or via email to the primary investigator. If you do not follow the researchers' instructions, they may end your participation in the study. If</p>

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		researchers believe there is a risk to your safety or health, they will end your participation in this study.
10	What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?	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 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 .
11	Will I be reimbursed or paid?	You will not be paid or reimbursed for participating.
12	What alternative procedures might benefit me?	No alternative procedures are available for this study.
13	Will my	NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law.

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<p>personal information be kept confidential?</p>	<p>You will be given a study number which we will use to manage your data. The consent form will contain the study number. This number will be the only link to the data collected. In the field, all the information that can identify you will be on a secure laptop computer; any paper records will be kept in a locked box with the study researchers. When we return from the field, paper forms will be kept in a locked file cabinet in a secure area at the NIOSH office and digital data will be stored in a restricted access computer folder.</p> <p>We will not disclose or provide your name or any such information or document that contains identifiable, sensitive information about you and that was created or compiled for purposes of the research, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, or to any other person not connected with the research, unless you consent to such disclosure.</p> <p>The records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, your identity will remain confidential.</p> <p>Monitors, auditors, the IRB, and/or the regulatory authorities will be granted direct access to your study records for verification of study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, you or your legally acceptable representative is authorizing such access.</p>
<p>14 Certificate of Confidentiality</p>	<p>This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.</p> <p>There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse,</p>

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		<p>communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.</p> <p>Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.</p>
15	<p>Will I or anyone else receive study results?</p>	<p>We will send a summary of the study results to your company and worker representative, such as a union if applicable at your workplace. We will not share results with your personal information with the company or worker representative/union.</p> <p>Clinically relevant research results will be offered to be shared with you. These include the results of the hearing exam if you participate in that exam. This exam can identify a hearing problem but cannot determine the cause of a hearing loss. We will offer your results to you at the end of the test and will offer to send you your results in the mail after the test. You can choose whether to receive your results. If hearing loss is identified, we recommend that you see a healthcare provider regarding your hearing loss if you have not already done so.</p> <p>If you participate in personal exposure monitoring, we will offer to send you the results of your personal exposure measurements. If you choose to receive your results, we will send a letter directly to you and will not send it to your employer or worker representative.</p> <p>The sample analysis may take 6–9 months, so there may be a lengthy delay before you receive your results. In the letter, we will compare your exposure results to occupational exposure limits for noise and the chemicals being studied, including NIOSH Recommended Exposure Limits.</p> <p>If you want an electronic copy of the study summary report, please check the box below and provide an email:</p>

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		<input type="checkbox"/> Send me an electronic copy of the summary report. Send it to me at the following email address: <hr style="width: 20%; margin-left: 0;"/> <input type="checkbox"/> Do not send me an electronic copy of the summary report
16	Will my personal information or samples collected from me be used in other research?	<p>The information that we collect from you may be used in future research studies. We believe that this information from this study will aid in future OGE studies. One example may include efforts to evaluate prevalence of hearing loss across workers in this industry. Such efforts will be useful in tracking improvements in the industry in the future. We will not share your personally identifiable information with other researchers.</p>
17	Is this a Clinical Trial?	<p>No, this is not a clinical trial.</p>
18	Did you receive all necessary information?	<p>We want to provide you with all the information you need to decide if you want to participate in this study.</p> <p>If you did not receive enough information to be able to decide or want to discuss any of this information, please inform the NIOSH staff.</p>
19	Who can I talk to if I have more questions?	<p>For questions about the research study, contact the principal investigator, Bradley King at bradley.king@cdc.hhs.gov or 303-236-5933.</p> <p>For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591.</p>

