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

Consent to be in a Research Study

Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction

1	**Key Information Summary**	The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health and is part of the Centers for Disease Control and Prevention (CDC). NIOSH is conducting a study to understand how fatigue affects U.S. onshore oil and gas extraction (OGE) workers. You are being invited to participate in this study where we will conduct fatigue assessments with 80 workers that consist of the following activities over a work rotation: o One initial survey collecting information on you, your work, commute, and general sleep health o Brief surveys at the beginning and end of each workday o Daily alertness testing on a tablet o Sleep health measurements through wristband sensor You will be asked to give permission to take part in the study. **Participation in this research is voluntary.** You can stop your participation at any time without any consequences. There is a small risk that information collected could be compromised. No information identifying you will be collected in any of the activities mentioned above We will release summaries of information we collect in reports, presentations, and publications. Only NIOSH staff who are involved in this research will have access to the data. While there is no direct benefit, participation in this study will help identify factors that are associated with fatigue and provide information to develop policies or practices to prevent worker fatigue. You may be eligible to receive a token of appreciation of a $50 gift card for participating in this study. You may want to participate in this study to help companies like yours understand practical ways to reduce the hazards associated with fatigue and improve working conditions for you, and workers like you. However, you may not want to participate in this study if you are concerned about increasing the burden of work during your workday or concerns about your information being released and used against you. The study team would like to reassure you that the benefits of participating in this study outweigh the risks and precautions have been taken to minimize these concerns.

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2	**Who is conducting the study?**	The NIOSH is a federal agency that studies worker safety and health part of the CDC.
3	**What is the purpose?**	The purpose of this research is to learn more about how fatigue affects workers, identify work factors that contribute to fatigue, and learn about fatigue mitigation strategies that are in place.
4	**What will I do?**	Participation in the fatigue assessment consists of daily surveys and alertness testing at the beginning and end of your workday, and wearing a wristband sensor every day to measure your sleep health over a work rotation. You will have the option to sign a voluntary General Photo Release Form, which, if signed, would give the research team permission to take photos of you during the data collection period. These photos will be solely used for health communication purposes.
5	**When, where, for how long will I be needed?**	We will conduct this study during a two-week period at your worksite. You will be asked to participate for a work rotation. Your participation will occur during regular work hours and consist of: • 15 minutes on the first day for the training on the study • 15 minutes on the first day for the baseline survey • Approximately 10 minutes each day for the daily surveys and alertness tests • The wristband sensor will be worn continuously, including while sleeping, for the work rotation.
6	**Are there any risks from participating in the study?**	There is very little risk to you if you take part in this study. There is a small risk of that the information you provide could be accidentally released. However, we will not collect any personally identifiable information to minimize this risk. We will identify your responses by a unique code that cannot be linked back to you and only report summaries of all the information that is collected. We will not release your individual information to your employer. Only NIOSH staff who are involved in this research will have access to your responses. Physical injury or harm in participating in this study is not likely. There is also a small risk of harm or discomfort from wearing the wristband sensor during the data collection period. Wearing the device on your wrist all day may be uncomfortable. And, while it is not common, wearing it on your wrist for a long period of time could cause a skin rash for people with sensitive skin. If this happens, you will not be asked to keep wearing the device on your wrist. A possible solution is to clean the device by wiping it down with water or a small amount of rubbing alcohol. If, however, the problem continues, we suggest you remove it from your wrist and contact a member of the study team to discuss the issue and to determine whether you would like to continue

		participating in the study. Trained study team members will teach all participants on the wristband sensor use and wristbands will not be worn during activities deemed high risk by the employer. There is a very small risk you could get a respiratory infection (e.g., COVID-19, influenza) through an in-person interaction while participating in this study. To minimize your risk of exposure to viruses and maximize your protection against infection, NIOSH researchers follow COVID-19 and other relevant respiratory infectious disease guidance for CDC and NIOSH staff and workplaces. If NIOSH researchers see something that poses an imminent danger to yourself or others, the researchers will immediately notify you, other workers, and the management at your company.
7	**Are there other benefits?**	You will not receive any direct benefits from participating in this study. Your participation in this research will help to better understand how fatigue affects OGE workers and identify factors to consider when developing and implementing fatigue management strategies in the industry.
8	**Is my participation voluntary?**	Your participation in the study is voluntary. You may choose to participate in some or all portions of the study and answer any or all questions. You may decline to participate or drop out at any time, for any reason, with no penalty or loss of benefits to which you are otherwise entitled.
9	**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.
10	**Will I be reimbursed or paid?**	If you complete the baseline questionnaire, at least one pre-shift or post-shift questionnaire per day, one PVT test per day, can attest to wearing the actigraphy watch for at least 5 nights, and return your assigned actigraphy watch you eligible to receive a $50 gift card.
11	**What alternative procedures might benefit me?**	No alternative procedures are available for this study.

12	**Will my personal information be kept confidential?**	NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. Your name will only be collected on this informed consent document and for the purpose of assigning and tracking the actigraphy wristbands. Any personal information we collect from you will be kept confidential and secure. We will not ask you to give us information that could expose your identity. Monitors, auditors, the institutional review board which is an administrative body established to protect the rights and welfare of human research participants, or the regulatory authorities may be granted direct access to your study records for verification of study procedures or data. This is not a violation of the confidentiality of your data , by signing a written informed consent form, you are authorizing such access. At no point will your name be associated with, stored along with, or in any way connected to the research data we collect (for example, the results of your sleep health measurements or the surveys you have filled out). Any publications or reports using the data collected as part of the research study will preserve the confidentiality of your data and your identity.
13	**Certificate of Confidentiality**	This research project has a Certificate of Confidentiality from the 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. 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, 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. 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.
14	**Will I or anyone else receive study**	Responses from all study participants will be pooled and we will create a summary report that can be shared with oil and gas industry health and safety organizations. We will not share individual details of your participation with

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	results?	anyone. You may also request the summary results.
15	**Will my personal information or samples collected from me be used in other research?**	We will remove your name and other identifiers from the information that we collect during the study and then use the information for future research studies without asking you for additional consent. We may also remove identifiers from the information that we collect and then share it with other researchers without asking you for additional consent.
16	**Is this a Clinical Trial?**	This is not a clinical trial.
17	**Did you receive all necessary information?**	Is there anything about this research study that is unclear to you, or you would like to discuss?
18	**Who can I talk to if I have more questions?**	For questions about the research study, contact the principal investigator, *Alejandra Ramirez-Cardenas* at ARamirez-Cardenas@cdc.gov or 303-236-5957. 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.
19	**Your signature**	The study was explained to me. My questions were answered. I agree to participate in the fatigue assessment component of the study. _____ Printed name of participant _____ Participant signature Date I have accurately described this study to the participant. _____ NIOSH representative signature Date