

Informed Consent for Women Mine Workers



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

Consent to be in a Research Study

Developing a Framework to Identity and Address Hazards Unique to Women in Mining

1	Who is conducting the study?	<p>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).</p> <p>Our website is: https://www.cdc.gov/niosh/index.htm</p>
2	What is the purpose?	<p>The purpose of this research study is to hear from women mine workers about hazards and risks they encounter while working. The goal of this study is to use that information to determine what changes are needed to make mining work systems safer, healthier, and more supportive for women workers.</p>
3	What will I do?	<p>You will participate in an in-person or virtual focus group and then you will be asked to take a short survey. We will schedule you for a focus group on a day/time that is convenient for you. If the focus group is online, you will be sent a Microsoft Outlook calendar invitation for the date and time, which will contain a Zoom for Government web link. The focus group will last approximately 90 minutes. You will be asked questions about your role at work, different hazards and risks, and potential solutions. The survey will take approximately 5-7 minutes to complete and will include demographic and work history information. You are free to answer any question we ask however you like. The audio of the focus group will be recorded, and there will be 1-2 other research staff attending to take notes. Once we finish asking our questions, you will get to ask us any questions you might have. After we end the session, your participation in the study will be complete.</p>
4	When, where, for how long will I be needed?	<p>When: at a date and time that is convenient for you</p> <p>Where: a private location in an office or classroom (for an in-person focus group) or any location where you have phone or internet access (for a virtual focus group).</p> <p>How long: Total of 100 minutes (90 min focus group, <10 min survey)</p>
5	Are there	<p>This study has minimal risk. The only risks you may experience are</p>

	<p>any risks?</p>	<p>potential discomfort with questions and the risk of the loss of confidentiality.</p> <p>You are free to answer as many or as few questions as you would like, and you may stop the focus group at any time, for any reason. Giving your verbal consent to participate does not mean you have to answer every question we ask, and you don't have to tell us the reason you don't want to answer a question.</p> <p>We have taken every reasonable precaution to keep your information secure. We will take notes of your responses but will not include any identifying information such as your name or the name of the company that you work for. Focus groups conducted virtually will use Zoom.Gov, which has a high level of security authorization. To ensure accurate data collection, we will take an audio recording of your responses but will not include any identifying information on the recording. After the audio recordings are transcribed, we will destroy the recording. There is a very small potential for a data security breach, but we will de-identify transcribed data so it is unlikely that any data can be directly linked to you.</p> <p>For participants of in-person focus groups, there is a very small risk that 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.</p>
6	<p>Is my participation voluntary?</p>	<p>Your participation in the study is voluntary. You may choose to 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.</p>
7	<p>What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being</p>	<p>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.</p>

	conducted?	
8	Will I be reimbursed or paid?	You will not be reimbursed or paid for your time.
9	Are there other benefits?	Participants will receive no direct benefits. This research could lead to improving working conditions for women in the mining industry. Highlighting health and safety issues that affect women will inform actionable items for the industry and potential future NIOSH research to address health and safety disparities for women mine workers. Otherwise, no other potential benefit exists for participating.
10	What alternative procedures might benefit me?	No alternative procedures are available for this study.
11	Will my personal information be kept private?	<p>We will not be collecting or recording any personal identifiable information. We will use and disclose your information only as described in this form and in our Notice of Privacy Practices. Your information will be kept private and secure. Recorded notes and transcripts will be maintained on secure NIOSH servers. All notes and transcripts will be deidentified.</p> <p>The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigators of this study by phone or in writing. If you contact the Principal Investigators by phone, you must follow-up with a written request that includes the name of the study and your contact information. The names of the Principal Investigators and their email addresses and phone numbers are on located at the bottom of this consent form. If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.</p> <p>As is common with focus group data, we may use non-identifying quotes from your focus group transcript when reporting results of the study to the public. These quotes will be used as examples of themes that occur across different focus groups. For example, we will not</p>

		<p>quote you when you talk about specific aspects of your mine or management practices which could identify you to people reading the report, but we may quote how you describe certain work-related hazards or risks, or general challenges of putting a policy or mitigation measure in place. Please let us know if you do not wish for us to use any quotes from your transcript when reporting results.</p> <p>Transcribed focus group data will be kept for approximately 5 years. These research records will be maintained at the CDC/NIOSH Spokane Research Laboratory in Spokane, WA or the Pittsburgh Research Laboratory in Pittsburgh, PA in accordance with current records retention requirements. We will destroy research data kept on backups, but we may not be able to destroy data that was saved on the institution's server logs even after this research has been completed. We will destroy your research data at the end of the study, meaning we will not retain your information in coded or other form.</p>
12	Certificate of Confidentiality	<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, 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>
13	Will I or anyone else receive study results?	<p>If you want, we can send you a copy of the report once it has been published by the journal. If this is something you would be interested in, please provide your contact information to project staff at the conclusion of your focus group.</p>

14	Who can I talk to if I have more questions?	<p>For questions about the research study, contact the principal investigators:</p> <ul style="list-style-type: none"> • Casey Stazick at cstazick@cdc.gov or 509.354.8080 • Brianna Eiter at beiter@cdc.gov or 412.386.4954 <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>
15	Resources	<p>Substance Abuse and Mental Health Services Administration (SAMHSA) National Helpline – Call 1-800-662-4357, it's free, confidential, and operates 24/7.</p> <p>Equal Employment Opportunity Office – Call 1-800-669-4999 or Email info@eeoc.gov to receive information about the laws EEOC enforces and/or to file a charge of employment discrimination.</p> <p>Call 911 if the crisis is a life-threatening emergency. Make sure to notify the operator that it is a psychiatric emergency and ask for an officer trained in crisis intervention or trained to assist people experiencing a psychiatric emergency.</p> <p>Suicide & Crisis Lifeline (formally known as the National Suicide Prevention Lifeline) – Call 988 to speak with a trained crisis counselor.</p> <p>Crisis Text Line – Text NAMI to 741-741 to connect with a trained crisis counselor to receive crisis support via text message.</p> <p>National Domestic Violence Hotline – Call 800-799-7233 to speak with trained experts who provide confidential support to anyone experiencing domestic violence or seeking resources and information.</p> <p>National Sexual Assault Hotline – Call 800-656-4673 to connect with a trained staff member from a sexual assault service provider in your area that offers access to a range of free services. Crisis chat support is also available at https://hotline.rainn.org/online.</p>