



Consent to be in a Research Study

Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners

1	Who is conducting the study?	NIOSH is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).
2	What is the purpose?	I am currently conducting research to better understand why miners do or do not get voluntary black lung screenings. The research will be used to inform an intervention to improve early detection and medical surveillance programs.
3	What will I do?	You will participate in a focus group and share your thoughts and suggestions on black lung screenings in a group discussion. With your permission, the discussion will be recorded with an audio device. You will also complete a survey to give us information about you and your experiences.
4	When, where, for how long will I be needed?	The focus group will be conducted during the conference, meeting, or event in a location such as a classroom, private area, or conference room in the event venue. The focus group will take 30 to 60 minutes.
5	Are there any risks?	<p>This study poses minimal risk to participants. The greatest potential risk involves your confidentiality. The researcher will ask participants to keep the information shared during the discussion confidential. However, the researcher cannot guarantee that the information you disclose during the group discussion will not be shared by other group members following the discussion.</p> <p>Due to this potential risk, researchers ask that you do not disclose sensitive or personal information that you do not want shared after the focus group discussion.</p>
6	Is my participation voluntary?	The study is voluntary. You may choose to be in the study or not. You may choose to answer any or all questions. You may drop out any time for any reason without consequences to you.

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7	What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?	<p>NIOSH will summon emergency medical aid by calling 911. 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.</p>
8	Will I be reimbursed or paid?	<p>You will not be paid or reimbursed for participating.</p>
9	Are there other benefits?	<p>You will not receive any direct benefits for participating in this study. Your participation will help to inform research that may help others.</p>
10	Will my personal information be kept private?	<p>Information collected by the researcher will be anonymous. However, researchers cannot guarantee that other group members will keep your information private.</p> <p>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.</p>

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11	Will I or anyone else receive study results?	Results from this study may be presented in final reports, publications, and presentations. The results will be presented as summarized themes, aggregate data, or anonymous quotes.
12	Who can I talk to if I have more questions?	For questions about the research study, contact the principal investigator, Dr. Emily Haas at WCQ3@cdc.gov or (412) 386-4627. 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.
13	Your verbal consent	Please verbally give your consent by saying “Yes” if (1) the study has been explained to you, (2) your questions have been answered, and (3) you agree to participate in the study. I understand that audio of the discussion may be recorded by the researcher to assist with the accuracy of your responses. These recordings will be kept by the researcher in a password protected file. I understand that only the research team will have access to these recordings and that they will be transcribed and destroyed within 12 months. You have the right to refuse the audio recording. Please state “Yes” to consent to the audio recording or “No” to refuse.

Updated June 3, 2019

