



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

Consent to be in a Research Study

Evaluation of Heat Stress Training Module

1	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). Our website is: https://www.cdc.gov/niosh/index.htm
2	What is the purpose?	The purpose of this research study is to evaluate a NIOSH heat stress training module and determine what training resources are needed.
3	What will I do?	<p>You will participate in in-person or online interviews. We will schedule the interview at a date/time that is convenient for you. If the interview 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 post-preparation interviews will last 15-20 minutes and will cover whether you felt adequately prepared to provide the training given the training module resources. We will conduct up to 5 interviews at three different time points:</p> <ul style="list-style-type: none"> • At the beginning of the study (30 minutes) • After you prepare for the training but before you give the training (20 minutes) • Immediately following the first, second, and last training sessions (40 minutes for the first interview, 30 minutes for the last two interview) <p>Depending on your role and how many trainings you give, you may only participate in two interviews. Depending on whether your employer uses multiple trainers, we may conduct interviews among small groups of trainers.</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: Any private location in your offices (for an in-person interview) or any location where you have phone or internet access.</p> <p>How long: Total of 150 minutes for interviews</p>
5	Are there any	This study has minimal risk. The only risks you may experience are potential discomfort with questions and

	<p>risks?</p>	<p>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 interview at any time, for any reason. Signing this form 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. Interviews conducted virtually will use ZoomGov, 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 interviews, 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 conducted?</p>	<p>NIOSH will follow mine protocols. 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>

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. Knowledge gained from this study can help NIOSH develop more effective heat stress training resources.
10	What alternative procedures might benefit me?	No alternative procedures are available for this study.
11	Will my personal information be kept private?	<p>Your information will be kept private and secure. Recorded notes will be maintained on secure NIOSH servers. All notes will be deidentified. These de-identified recorded notes may be used for future planning work for the Miner Health Program but will not be used in any way that can identify the participant.</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. 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.</p>
12	Will I or anyone else receive study results?	Information from this evaluation will be used by NIOSH to determine what further resources are needed for heat stress training in the mining industry. We will provide you with a brief verbal and written report of your results. We do plan to publish a summary of our finding as a journal article.

13	Who can I talk to if I have more questions?	<p>For questions about the research study, contact the principal investigator, Kristin Yeoman at vij6@cdc.gov or 509-354-8067.</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>
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