



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

Co

## Consent to be in a Research Study

### *Health-related changes in cognitive performance*

#### Field component

### *Read Me First!* – Important Key Information

- We're doing a study on 59 participants to find out how heat affects miners' concentration; this is important because heat exposure can cause heat strain, which is the body's response to a heat load. Heat strain can lead to heat illness, which is a condition where the body cannot cool itself, leading to symptoms such as cramps, headaches, dizziness, and nausea or vomiting. Heat strain can also increase the risk of injuries, which is partly because of decreased concentration
- As part of this study, we also want to find out what heat strain looks like in underground and surface miners, so that we can design future studies to evaluate relevant aspects of heat strain to mining
- We would like to know if there is a way to use heart rate, body temperature, and air temperature/humidity to predict when workers' concentration starts to decrease
- Being in our study is 100% optional; there are no penalties for not signing up or for withdrawing
- Some health conditions may prevent you from being eligible for the study so you must complete a health questionnaire to determine if you can safely participate
- You cannot participate in the study if you are pregnant or if you have a condition that prevents you from swallowing a temperature pill
- The study will take place during 2 shifts after today
- Before each shift, we will need a urine sample to make sure you are hydrated.
- You will swallow a pill that measures your body temperature, and you will wear a sensor to measure your heart rate
- We will give you an instrument to place in your work area so we can measure the environmental temperature and humidity
- You will be provided with a smart phone to complete brief questions and an attention test
- You will receive alerts about 4 times during your shift to remind you to take the test, but you do not have to take the test when you receive the alerts
- The attention test will only take 6 minutes, and you will take it twice during your shift, once when you feel like your body temperature is normal and once when you feel like your body temperature is high
- Before your shift starts and after your shift is over, we will give you two short questionnaires that add up to about 10 minutes; these questions ask about your recent health
- In total, you will spend about 45 minutes on the study each day you participate, but only about 12 to 15 minutes will be spent during your shift
- You can stop the study at any time
- You will receive your individual results if you would like them
- The main reason to participate is that we will gain important knowledge that will be used to help miners decrease heat strain in their jobs. The knowledge will also be used to develop safety guidelines for heat exposure in mines that may improve miners' safety in the future.

#### **There are several reasons you may not want to participate in the study:**

- The 6-minute attention tests will happen during your work day, so you may not want to be distracted by taking the tests
- You will need to swallow a temperature pill
- Like with all studies, there is a small chance that your data could be compromised, but we have very

high security standards and will use coded IDs rather than names when collecting and storing your data

1	<b>Who is conducting the study?</b>	<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). Our website is: <a href="https://www.cdc.gov/niosh/index.htm">https://www.cdc.gov/niosh/index.htm</a></p>
2	<b>What is the purpose?</b>	<p>The purpose of this research is to study whether heat exposure affects miner performance and concentration. We would like to know if there is a way to use heart rate, temperature, and air temperature/humidity to predict when workers' ability to concentrate begins to decrease. We also want to find out where heat strain is most common among underground and surface miners.</p>
3	<b>What will I do?</b>	<p>We will evaluate you over 3 visits. The first visit we will orient you to the study and get baseline information. The second and third visit we will collect data during your shift. These visits may be consecutive or there may be time between them, depending on your work schedule.</p> <p><b>Visit 1</b> On the first day of the study, NIOSH staff will orient you to the study, get baseline health information, and measure your height and weight. This will take place in a private area of the mine site.</p> <p><b>Questionnaire</b> You will fill out a questionnaire about your health history on paper or on a tablet. The questionnaire will ask questions about your background, health conditions, medication use, alcohol use, history of heat illness, physical fitness, and mental health. We will use these responses to provide information on risk factors for heat strain and what could lead to decreased work performance.</p> <p><b>Cognitive test</b> During the initial orientation, we will demonstrate the attention test to you. You will practice the test and then take it once so we have an idea of your baseline attention level.</p> <p><b>Who can't participate</b> Pregnant women cannot participate. Additionally, because we use temperature pill to keep track of your body temperature, medical conditions that prevent you from swallowing or passing the temperature pill (i.e., esophageal disorders, obstructive or hypomotility disorders of the gastrointestinal tract, previous gastrointestinal surgery, disorders of the gag reflex, having pacemaker or implantable cardioverter defibrillator, planning to have MRI within 2 days of study) will stop you from being in the study.</p> <p><b>Visits 2 and 3</b> You will be tested during your shift at work for a total of two shifts. We will work with you to determine the best shifts to do the testing.</p> <p><b>Urine test for hydration</b> Prior to starting your shift, you will provide a urine sample that will be only be</p>

		<p>tested to see if you are hydrated. We will not test for anything else and will promptly discard the urine.</p> <p><b>Equipment set-up</b>  You will swallow a temperature pill before proceeding to your work site. You will put on a chest strap to record your heart rate. We will equip you with a smart phone and orient you to the application. You will also be given ear buds. These ear buds will alert you to begin the assessments at the appropriate time. They also provide hearing protection.</p> <p>You will be given an instrument that measures environmental temperature and humidity and instructed on how to place it in your work area. The instruments will be there during your entire shift.</p> <p><b>Testing during work activities</b>  You will then proceed to your work station and begin your normal work tasks. The ingested temperature pill and chest strap will measure your body temperature and heart rate throughout the entire shift.</p> <p>All data during the underground shift will be collected by the smart phone application. The smart phone will alert you using a combination of sounds and vibration. The smart phone application will be set to collect data twice during your shift.</p> <p>The alerts will sound four times during your shift. These alerts are just to remind you to complete the tests, but you do not have to complete the tests when you get the alerts. You will complete the attention test once when you feel that your body temperature is normal and once when you feel that your body temperature is high. You will begin each test by tapping on the 'Begin Day' button in the smart phone application. The application will lead you through two questions and then will start the attention test. After the test is complete, you will return to your work tasks.</p> <p><b>Questionnaire before your shift and at end of work shift</b>  You will take two brief questionnaires, one before your shift and one at the end of your shift. These questionnaires will ask for information on some things that can affect heat strain and will take about 10 minutes to complete.</p> <p><b>Urine test for hydration at end of shift</b>  At the end of each shift, the researchers will collect the smart phone, chest strap and data recorder, and environmental monitors, and you will provide another urine sample to be tested to determine how hydrated you are.</p>
4	<p><b>When, where, for how long will I be needed?</b></p>	<p>We will need time before you begin your shift to set up the study, and time after your shift for you to take the post-study questionnaire and return the equipment (approximately 10-15 minutes each time). Only about 12 minutes of the study will take place during work hours. The total time expected is approximately 45 minutes each day.</p>

5

**Are there any risks?**

**Work activities**

NIOSH investigators will not ask you to perform additional work on top of your usual activities. It may be distracting to take the attention test and answer questions on the app while you are in your work area. To decrease the risk of distraction, especially if you are working in a hazardous area, you will be asked to wait to take the test until you feel it is safe to do so.

**Elevated core body temperature**

National and international organizations such as NIOSH, ACGIH, and WHO recommend that unacclimatized workers' core body temperatures should not exceed 100.4 °F. Based on previous studies, you could experience temperatures beyond these recommended limits while on the job.

**Identity of participants**

We won't be able to keep the identity of those who decide to participate in the study private because others will see you taking the tests. You may therefore have loss of personal privacy if you work with colleagues who can see you participating. However, no one else will be able to access your data.

**Capsule ingestion**

Risks associated with the ingestible temperature pills involve inability to swallow the capsule in persons with esophageal disorders; inability to pass the capsules in persons with obstructive or hypomotility disorders of the gastrointestinal tract, previous gastrointestinal surgery, or swallowing/gag reflex disorders; or interference of the capsule with pacemakers, implantable cardioverter defibrillators, or MRI scanning. You may also find it difficult to swallow the pill. Participants will not necessarily know when they have passed the temperature capsule, because they will not always be able to see the capsule in their stool. They will be instructed to call their health provider if they have constipation after test days, along with any of the following symptoms: substantial bloating, feeling like they need to pass stool but are unable to do so, nausea or vomiting, inability to pass gas, or abdominal pain. It is not possible to predict when someone will pass the pill because it depends on their usual bowel habits (i.e., someone who has a bowel movement once a day or more frequently will probably pass the pill within 24 hours, whereas someone who has bowel movements every 2-3 days will pass the pill more slowly).

**Data security/loss of confidentiality**

Data collection will be on smart phones, allowing you to complete the questions and attention tests in private at your work area. Data will be collected off network, and the phone apps will be password protected. You will receive instructions on how to use the phones.

Another risk of participating is a possible loss of confidentiality of your records if an unauthorized person accesses the data. However, NIOSH takes your privacy seriously and every care will be taken to keep your information safe. All questionnaires will be identified with unique identifiers rather than personally identifiable information (PII), and the key (with names and unique identifiers) will be maintained on paper in a locked cabinet in a secure NIOSH facility. You will not be identified by name to other researchers and study results will be shared as a group. After data collection for all participants has been completed and data are checked for completeness and quality, the link between your name

		<p>and unique identifier will be destroyed.</p> <p><b>Cognitive tests</b> No risks are anticipated from taking the attention tests.</p> <p><b>Observing imminent danger to workers</b> While at the mine, if NIOSH investigators observe a situation that presents an imminent danger to workers, we will immediately advise the employer, owner, operator, or agent in charge as well as those who are in immediate danger. Unless the company mitigates the issue immediately, we will also inform the appropriate state agency or MSHA district officer.</p>
6	<b>Is my participation voluntary?</b>	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.
7	<b>What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?</b>	NIOSH will follow mine protocols. We will summon emergency medical aid by calling 911 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 <a href="https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html">https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html</a> .
8	<b>Will I be reimbursed or paid?</b>	No, you will not be reimbursed for your time. Data collection will only occur during your normal work shift, but you will spend approximately 10-15 minutes before each shift to prepare for the study and 10-15 minutes at the end of each shift to turn in equipment.
9	<b>Are there other benefits?</b>	Participants will receive no direct benefits. Knowledge gained from this study can help NIOSH and mines to prevent heat strain among all workers.
10	<b>What alternative</b>	No alternative procedures are available for this study.

	<b>procedures might benefit me?</b>	
<b>11</b>	<b>Will my personal information be kept private?</b>	<p>Your information will be kept private and secure. Recorded notes will be maintained in locked file cabinets in a secure NIOSH building. After all questionnaire and measurement information has been recorded and verified electronically, all forms containing participant names will be destroyed according to CDC policy. We will not use your contact information for any other purpose and will destroy it after the study has been completed. Only CDC researchers and research partners will be able to access your information.</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> <p>Additionally, this research is covered by an Assurance of Confidentiality. NIOSH requested and received authorization under 308(d) of the PHS Act (42 U.S.C. 242 m (d)) to give assurance of confidentiality for these data. We will not disclose information in a way that will allow for the identification of an individual mine worker or entity providing data (e.g. mine operator) unless consent has been obtained, and we will not disclose information to any person or agency not entitled to receive it. We will provide you with further information if you so desire.</p> <p>HHS System of Records Notices (SORNs) are required for studies in which the Privacy Act is applicable. As required by The Privacy Act, HHS publishes SORNs to provide public notice of the records it maintains about individuals. Each SORN describes the types of information contained in the records, the legal authority for collecting and maintaining the records, how the records are used within HHS, and the purposes for which HHS may disclose the records to non- HHS parties without the individual record subject's consent. The SORN that covers this study confidentiality is 09-20-0117 Medical and Test Record Results of Individuals Involved in NIOSH Laboratory Studies.</p> <p>Information or biospecimens (e.g. urine) collected as part of this research will not be used or distributed for future research studies.</p>
<b>12</b>	<b>Will I or</b>	<p>We will provide you a copy of your attention test results at the end of the study, if you wish to receive them. These results are for your interest only but are not clinically relevant. There are no "abnormal" or "normal" results for the attention</p>

	<p><b>anyone else receive study results?</b></p>	<p>tests, so you will not be able to make changes to your work tasks after reviewing the results. We will also provide you with your maximum temperatures during your shifts, if you wish to receive them. These temperatures are not clinically relevant, meaning that there is nothing a health provider would do with them. If your temperature is very high, this information can be used to determine if it might be helpful to cool down at various times during your work shift. We will mail the results to you after verifying with you that we have your correct address, if you decide to receive them.</p> <p>You will have the option of calling the medical officer with any questions. We will also present aggregated results during a group debriefing session for all participants who are interested in attending. We will ensure that aggregated results cannot be used to identify the results of any individual participant. You may opt out of receiving results.</p>
<p><b>13</b></p>	<p><b>Who can I talk to if I have more questions?</b></p>	<p>For questions about the research study, contact the principal investigator, Kristin Yeoman at <a href="mailto:vij6@cdc.gov">vij6@cdc.gov</a> 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>
<p><b>14</b></p>	<p><b>Your signature</b></p>	<p>The study was explained to me. My questions were answered. I agree to be in the study.</p> <p>_____</p> <p>Printed name of participant</p> <p>_____</p> <p>Participant signature <span style="float: right;">Date</span></p> <p>I have accurately described this study to the participant.</p> <p>_____</p> <p>NIOSH representative signature <span style="float: right;">Date</span></p>
<p><b>15</b></p>	<p><b>Additional consent</b></p>	<p><input type="checkbox"/> No, do not send me the results of my core body temperature.</p> <p><input type="checkbox"/> Yes, please send me the results of my core body temperature</p> <p style="padding-left: 20px;"><input type="checkbox"/> by email</p> <p style="padding-left: 20px;"><input type="checkbox"/> by postal mail</p> <p><input type="checkbox"/> No, do not send me the results of my attention test.</p> <p><input type="checkbox"/> Yes, please send me the results of my attention test</p>

		<p><input type="checkbox"/> by email</p> <p><input type="checkbox"/> by postal mail</p> <hr/> <p>Printed name of participant</p> <hr/> <p>Participant signature <span style="float: right;">Date</span></p>
--	--	---