

Heat-related changes in cognitive performance

Information Collection Request for Office of Management and Budget (OMB)
Review and Approval

Part A

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- The goal of the study is to assess the following: (1) whether a core body temperature threshold exists at which cognitive performance begins to decline, (2) factors that contribute to inter- and intra- individual variability in cognitive physiologic responses to heat, and (3) patterns of heat strain among miners in both surface and underground mines.
- The intended use for this data is to develop guidance and strategies to mitigate risk of heat strain among miners. This guidance will build on the strategies currently used by mining but will include information on how to incorporate personal factors and physiologic measurements into current heat strain monitoring and prevention practices.
- Data will be collected in both the field and in a laboratory environmental chamber. The field study is an observational study where miners will ingest capsules and wear a bio-harness to measure core body temperature and heart rate while performing their normal activities during two work shifts. The laboratory study is also an observational study where workers will complete exercise testing in an environmental chamber to raise core body temperature while heart rate and core body temperature are monitored and cognitive performance is tested.
- The subpopulation to be studied in the field study include surface and underground mine workers. The subpopulation to be studied in the environmental chamber study include surface and underground mine workers, construction workers, and structural and wildland firefighters.
- Descriptive analyses will be conducted for both the field and environmental chamber studies. Data from the field study will be analyzed by categorizing core body temperatures into zones and then calculating mean, maximum, and range of number of times core body temperature falls into a zone. Data from the environmental chamber study will be analyzed using a log-logistic time to event frailty model, generalized linear mixed models, and time series analyses.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a new information collection request from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, seeking a three year approval data collection for a public health study. The proposed information collection will provide much-needed information on burden of heat strain among U.S. miners, as well as information needed to develop strategies and guidance to reduce heat strain in the mining industry. This study is being conducted by the National Institute for Occupational Safety and Health. NIOSH, under P.L. 91-173 as amended by P.L.

95 -164 (Federal Mine Safety and Health Act of 1977, Appendix A), has the responsibility to conduct research to improve working conditions and to prevent accidents and occupational diseases in underground coal and metal/nonmetal mines in the U.S.

Heat strain is an increasing problem among many industries, including mining. As mines expand into deeper and hotter environments, heat strain among underground miners is likely to increase. Furthermore, heat waves are expected to increase in frequency, length, and intensity (NOAA, 2017), posing a substantial risk to surface miners. Heat strain can lead to a number of adverse health conditions of varying severity (e.g., heat syncope, heat rash, heat exhaustion, heat stroke). Additionally, studies have demonstrated associations between heat exposure and work injuries. Associations with heat-related injury have been described with respect to daily and seasonal ambient temperatures, worker behavior and unsafe practices, education level, and previous work injury (Xiang et al., 2014; Tawatsupa et al., 2013; Fogleman et al., 2005; Knapik et al., 2002; Barreto et al., 1997; Ramsey et al., 1983). Although the underlying mechanism between heat exposure and injury is not precisely known, it likely involves a combination of fatigue and reduced cognitive and psychomotor function (Varghese et al., 2018). Because of these factors, increasing heat stress among both underground and surface mines could negatively affect both the health and safety of mine workers.

Despite the increasing importance of heat stress in mining, few studies have focused on heat strain among U.S. miners. However, the few studies that are available have demonstrated that miners often exceed a core body temperature of 38 °C during work activities (Lutz et al., 2014; Yeoman et al., 2019). Standards have been developed to protect workers from heat strain. The World Health Organization (WHO), American Conference of Governmental Industrial Hygienists (ACGIH), and the International Organization for Standardization (ISO) have developed standards, guidelines, or threshold limits designed to prevent core body temperatures among workers from exceeding 38 °C (WHO, 1969; ACGIH, 2016; ISO, 2004). However, questions remain regarding duration and intensity of heat strain (NIOSH, 2016). Brief versus longer-term and intermittent versus continuous exposures to core body temperatures above 38 °C might have very different effects on health and safety (NIOSH, 2016). A better understanding of duration and intensity of heat strain among U.S. miners would help to focus future heat strain research to better serve the mining industry.

In addition to determining the patterns of duration and intensity of heat strain among U.S. miners, investigating the additional effects of heat strain beyond the risk of heat illness is an important step in improving miner health and safety. Studies have demonstrated associations between heat stress and cognitive deficits, but results are inconsistent. One factor relating to the inconsistency of study results is likely individual variability in heat tolerance. Physiologic heat strain is variable at a population level, and thus all persons whose core temperatures exceed 38 °C will not necessarily develop heat illness (NIOSH, 2016). Individual variability comprises both inter-individual factors such as age, sex, and chronic disease, and intra-individual factors such as medication use, fitness, and hydration (Notley et al., 2019). Many studies have not included sufficient information on the contributions of these factors to study results. Limited information exists on the interactions between various inter- and intra-individual factors in the development of heat strain (Notley et al. 2019). This individual variability likely affects the usefulness of heat stress indices that are currently used in many workplaces to prevent heat illnesses. The ability to mitigate heat-related adverse outcomes would likely be improved by a better understanding of which inter- and intra-individual factors are most important. This information could be used to develop algorithms or guidelines that incorporate these individual factors with physiological monitoring and the more routine measurements commonly used in heat stress indices.

In order to develop algorithms or guidelines that incorporate physiological monitoring, more information is needed on the specific characteristics of heat exposure that most affect cognitive function. It is unclear whether core body temperature or environmental conditions leading to varying perceptions of thermal discomfort are the driving factors of heat-related cognitive decline. Furthermore, questions remain regarding which characteristics of core body temperature are associated with cognitive dysfunction. Are there absolute temperature thresholds leading to cognitive decline, or is cognitive decline related to the rate of change of core body temperature or the fact that temperature is increasing or decreasing? Considerable variability in achieved maximum temperatures has existed in studies. Core temperature has not exceeded 38 °C in many studies, and some investigators have hypothesized that cognitive dysfunction does not occur until core temperatures of approximately 38.5 °C have been reached (Schmit et al., 2017). Other studies have demonstrated that cognitive dysfunction begins to occur at temperatures above 37.5 °C (Hancock and Vasmatzidis, 2003). Still other investigators posit that the factor that best predicts cognitive dysfunction is the relative change in core temperature over a period of time rather than the absolute temperature that is reached (Gaoua, 2010). Given the current standards from national and international organizations recommending that core body temperatures not exceed 38 °C in general, a better understanding is needed regarding the core body temperature characteristics that are most associated with declines in cognitive functioning.

Given the knowledge gaps in our understanding of patterns of heat strain in mining and in our understanding of heat-related cognitive changes, including the contributions of intra- and inter-individual factors to variability in heat tolerance and the effects of core body temperature on cognitive function, we aim to assess the following in our study: 1) Whether a core body temperature threshold exists at which cognitive performance begins to decline, 2) What factors contribute to inter- and intra-individual variability in cognitive and physiologic responses to heat, and 3) Patterns of heat strain among U.S. surface and underground miners.

The Federal Mine Safety and Health Act of 1977 authorized NIOSH to “conduct such studies, research, experiments, and demonstrations as may be appropriate to improve working conditions and practices in coal or other mines, and to prevent accidents and occupational diseases originating in the coal or other mining industry; to develop epidemiological information to (A) identify and define positive factors involved in occupational diseases of miners, (B) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (C) improve mandatory health standards; to study the relationship between coal or other mine environments and occupational diseases of miners.” (Appendix A).

The proposed program is a step toward meeting NIOSH and industry goals in addressing heat strain among miners. To prioritize future occupational safety and health research and prevention activities in each major industry sector, NIOSH organized national sector councils comprised of representatives from NIOSH, industry, organized labor, and academia. The Mining Sector Council (MSC) identified critical knowledge gaps and research needs in its National Mining Agenda in 2015. The proposed data collection will address several prioritized strategic objectives identified in the National Mining Agenda. The objectives directly addressed by this project include:

3.4 Reduce Stress-Based Diseases (e.g., heat- and cold-related)

3.4.2 Investigate thermal effects in mining

3.6 Improve Health Surveillance in Mining

Additionally, the NIOSH Mining Program has developed strategic goals to meet the objectives of the Mining Sector Council. The proposed data collection will address the following Mining Program strategic goals:

Strategic goal 1: Reduce mine workers' risk of occupational illnesses

Intermediate goal 1.3: Workplace solutions are adopted to reduce the effects of environmental factors on miners

2. Purpose and Use of Information Collection

Since mining is a hazardous environment, and heat strain contributes to the hazard, it is extremely important for NIOSH to collect this information as it is our goal to improve the health and safety of all mine workers. This data collection effort is currently funded by the NIOSH Mining Program through fiscal year 2022.

The purpose of this study is to collect information on burden of heat strain among miners as well as factors related to personal risk and core body temperature that contribute to individual variability in heat tolerance and to declines in heat-related worker performance. This information is not available in other data sources, including Mine Safety and Health Administration (MSHA) data. MSHA data is limited by underreporting of heat-related illnesses and does not include information on the contribution of heat exposure to injuries. A better understanding of duration and intensity of heat strain among U.S. miners would help to focus future research on those aspects of heat strain (i.e., short- vs long-term and continuous vs intermittent heat exposure) that could provide useful information in developing strategies to mitigate this hazard. Furthermore, a better understanding is needed on the most important factors contributing to individual variability in heat tolerance. This individual variability likely affects the usefulness of heat stress indices that are currently used in mining. Finally, this research will provide important information on the effect of core body temperature thresholds on individual variability and declines in cognitive performance. Because many heat indices are developed to prevent core body temperature in an average population from exceeding 38 °C, it is important to determine whether this threshold is useful. Specifically, a better understanding of whether there are absolute temperature thresholds above which cognitive function starts to decline, or whether there is variability in these thresholds depending on individual factors, is important to inform current mining practice, where in general, a one-size-fits-all approach to heat strain prevention is used.

The successful completion of this research will have several impacts. NIOSH will be able to use this research to develop guidance and strategies to mitigate risk of heat strain among miners. This guidance will build on the strategies currently used by mining but will include information on how to incorporate personal factors and physiologic measurements into current heat strain monitoring and prevention practices. Although it will not be directly measured, injuries related to heat strain could also be reduced. Information on the duration and intensity of heat strain among U.S. miners will also focus future NIOSH heat strain research on aspects of heat strain that are most relevant to mining. This research will also be useful for other occupations and industries dealing with heat strain, such as firefighting and construction.

The data collection will occur in both the field setting as well as in a controlled laboratory setting. For the field setting, 59 mine workers from underground and surface mines will be recruited. The majority of these mine workers will work in areas considered hot or warm within their mine sites. After completion of a pre-screening health questionnaire (Appendix C), mine workers will complete a baseline cognitive test, the 5-minute Psychomotor Vigilance Test (PVT) on a smart phone. They will be scheduled for assessments during two complete shifts. During each of the two shifts, they will complete two 6-minute assessments to include questions and the 5-minute PVT (Appendix D), for a total of four assessments over two shifts. All assessments will be taken by smart phone, which will alert them when to take the assessments. Prior to each of the two shifts, they will swallow a temperature pill to measure core body temperature (CBT) and place a bio-harness to measure heart rate (HR). Core body temperature and heart rate will be automatically measured and recorded by a Sensor Electronic Module (SEM) that will be attached to their bio-harness. They will also receive a monitor to attach to their persons that will measure and record environmental air temperature and humidity in their work areas. They will not be required to do anything while the CBT, HR, and environmental temperature/humidity are measured. At the end of their shift, they will complete a 10-minute questionnaire to obtain information on factors relevant to heat strain that vary over time: alcohol consumption over the past 24 hours, acute illness, medication use, sleep amount and quality during the night prior to testing, and number and type of shifts worked during the current shift rotation (Appendix E). They will also provide pre- and post-shift urine samples that will be used only to assess hydration status. The data will be used to assess whether core body temperature thresholds exist above which cognitive function declines, the factors associated with individual variability in heat tolerance, and the duration and intensity of heat strain among U.S. miners.

The laboratory study will take place within an environmental chamber, in which environmental conditions can be highly controlled. The participants for this aspect of the study are 30 mine workers, construction workers, and firefighters. To ensure that participants can safely complete the exercise protocol, a brief physical examination (i.e., heart and lung exam) (Appendix F) and health screening questionnaire (Appendix G) will be used to collect data on current health conditions and symptoms, as well as other factors relevant to heat strain. This information will be used to exclude persons who should not participate because of the study's physical demands. Additionally, persons aged ≥ 40 years and persons with diabetes or previously diagnosed kidney disease will undergo fingerstick testing using point-of-care testing for further risk stratification. Participants will complete exercise testing comprising alternating resistance and aerobic exercises, followed by questions on affect, fatigue, and sleepiness (Appendix H) and two cognitive tests taken by tablet or computer for a total of 11 minutes. They will complete a total of five rounds of exercises followed by cognitive tests over three days of testing. The first round will be performed at room temperature within the environmental chamber on the first day. The other four rounds will take place in hot conditions within the environmental chamber, on two separate study days separated by at least two weeks, for a total of two rounds per day. At the beginning of each of the study days, participants will complete a brief questionnaire (Appendix I) followed by two baseline cognitive tests. HR and CBT will be monitored during the entire time they are exercising and taking the cognitive tests. The data will be used to assess whether core body temperature thresholds exist above which cognitive function declines and the factors associated with individual variability in heat tolerance.

Only by better understanding heat strain patterns among U.S. miners and how personal and core body temperature-related factors are associated with worker cognitive performance will we be able to develop effective strategies to mitigate heat strain. Failure to acquire the data for the study would halt our efforts to assist the mining industry in improving monitoring and prevention of heat strain. The

mining industry will be able to use the information we obtain from this study to develop, adapt, and promote policies to reduce heat strain and heat illnesses and to improve miner safety. The information will be used by NIOSH and other researchers to guide interventions, health and safety promotion, and future heat strain research.

3. Use of Improved Information Technology and Burden Reduction

Data from the questionnaires and cognitive tests for the environmental chamber study will be collected in electronic format via tablets. Touchscreen technology will be used to improve response time, with the majority of questions in multiple choice format to allow miners to easily choose the appropriate response on the tablet screen. The electronic format will also enable the use of skip patterns for the questionnaires, which based upon preceding responses, presents the workers with only the questions that they need to answer, reducing the number of questions to which they must read and respond. Automatic recording of responses will result in automated data entry and minimal data cleaning, allowing for more rapid analysis by program staff. Program staff will be available while miners are completing the questionnaires to assist with technical problems, to answer questions that miners might have, and to read questions to miners with low literacy.

Data from the initial health questionnaire for the field study will also be collected in electronic format via tablets, with the same benefits described above. The rest of the data, including the questions and cognitive tests in the 6-minute assessments and the post-shift questionnaire, will be taken via smart phone. The smart phone application has been designed by NIOSH to work in conjunction with the core body temperature data and software to alert participants to take the 6-minute assessment when core body temperature reaches a designated threshold. The application was designed by a development team within the Pittsburgh Mining Research Division's Health Communication, Surveillance, and Research Support Branch to improve the efficiency of data collection. The smart phone app will allow for data collection to be done by the miners themselves, rather than requiring the presence of NIOSH investigators. When NIOSH investigators collect data in mines, they require the presence of the mine health and safety officers; by using the smart phone application, the mine health and safety officers will no longer need to be involved in data collection, freeing them to complete their usual work activities.

The questionnaires and cognitive tests for this study were used during both field and environmental chamber pilot testing and were well understood and received. The smart phone application was developed based on miner feedback after the pilot field study, and further evaluation of the application by a sample of the pilot field study participants demonstrated that this format of data collection was a substantial improvement over the previous format requiring NIOSH investigators to obtain the cognitive and questionnaire data directly by interacting with the miners in their work areas.

4. Effort to Identify Duplication and Use of Similar Information

To determine whether duplicate or similar information currently exists, a literature review was conducted, and we determined that no published results exist that specifically address the research questions proposed in this study. Although research has been conducted on the cognitive impacts of heat exposure, this research has not been conducted in miners. Additionally, few studies have looked at the influence of personal factors in heat tolerance, and to our knowledge, no studies have included the breadth of personal factors that our study is evaluating. These personal factors can contribute to

individual variability in heat tolerance, a major focus of our research. Finally, most heat strain studies involving mine workers have taken place outside the U.S. Few studies have looked at heat strain among U.S.-based miners. However, these studies have focused on limited characteristics of heat strain (i.e., maximum and mean core body temperature and heart rate) rather than on patterns of heat strain (i.e., how often and for how long core body temperature exceeds recommended thresholds). It is important to understand the patterns of duration and intensity of heat strain among U.S. miners in order to provide guidance to the mining industry that accounts for the workplace cultures, regulatory complexities, and work environments of U.S. mines.

5. Impact on Small Businesses or Other Small Entities

Both small (operations with 50 or fewer employees) and large mines will be included in the data collection for the field study in order to increase generalizability. In order to allow greater participation from mine workers in small mines, the amount of time required for data collection (~12 minutes total) during the shift is minimal. Because of the minimal interruptions during participants' shifts, mine workers from smaller mines that have less employee flexibility will have a greater chance of participation. Additionally, questionnaire and cognitive data have been held to the absolute minimum required for the intended use of the data. Participation for both mine operators and individual miners is strictly voluntary, and thus small mines that do not have the flexibility to participate will not be included. Use of questionnaires in electronic format will allow miners to participate more quickly and efficiently, and the minimum required questions for intended use of the data have been assessed and reviewed.

Miners, construction workers, and firefighters from work sites of all sizes will be included in the environmental chamber study. Small work sites will be unaffected by the environmental chamber study because we will only perform data collection on workers' days off.

6. Consequences of Collecting Information Less Frequently

This request is for three days of data collection per participant for each of the field and environmental chamber studies. Multiple days of data collection are necessary because one of the study's research objectives is to evaluate factors contributing to inter- and intra-individual variability in response to heat exposure. Thus, multiple days of data collection per participant are needed in order to evaluate differences in response to heat exposure over multiple days within the same subject, as well as between subjects. However, the three days of data collection occur within a limited time period, and further longitudinal analyses will not be performed after the three days of data collection per participant.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection complies with the guidelines of 5 CFR 1320.5. No special circumstances are associated with this activity.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Federal Register Notice was published in the *Federal Register* on February 25, 2020, vol.85, No.37, pp.10697-10698 (see Appendix B). No comments were received in response to the Federal Register Notice.
- B. NIOSH consulted with individuals outside the agency regarding this data collection to develop the study design and data analysis plan, as follows:

Alyssa Weakley, PhD, Cognitive Psychologist, Neuropsychology Postdoctoral Fellow in the Department of Neurology, University of California, Davis, alyweakley@gmail.com

Kimberly Honn, PhD, Assistant Research Professor, Washington State University, core faculty member of Sleep and Performance Research Center, kimberly.honn@wsu.edu

9. Explanation of Any Payment or Gift to Respondents

It is important to achieve the highest possible response rates during information collection. Compensation will not be provided for the field study participants because of the minimal amount of time required to participate. However, given the amount of time required to participate (i.e., half day on visit 1 and ~6 hours on visits 2 and 3), the demands placed on participants (i.e., performing work in a hot environmental chamber), the distance that participants must travel, and the fact that participants will complete study activities while they are off duty, all participants in the environmental chamber study will be compensated for participation \$35/hour and \$0.545 per mile. Compensation is necessary to obtain the needed participation for this study. During the environmental chamber pilot study, one participant mentioned that he would not have participated without the compensation because of the time requirements for the study. Without compensation, recruitment for the environmental chamber study will be severely limited.

10. Protection of the privacy and confidentiality of information provided by respondents

The NIOSH Information Systems Security Officer has determined that the Privacy Act does apply. Participation is voluntary. Participants will be asked to provide name, address, and social security number in order to write a check to compensate environmental chamber study participation. However, study investigators will not collect social security numbers; it will be collected by a NIOSH administrator, and information will be deleted after checks have been distributed.

Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded, conducted, or supported by CDC and the following is true: 1) activity constitutes biomedical, behavioral, clinical, or other research; 2) research involves human subjects as defined by 45 CFR Part 46; 3) individually identifiable (including coded) information or biospecimens will be obtained or used for research purposes; and 4) research involves information about an individual for which there is at least a very small risk, that some combination of

the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive “identifiable, sensitive Information” as defined by subsection 301(d) of the Public Health Service Act shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators and contractors conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. CDC will ensure: 1) that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and 2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act. Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens.

- All research subjects will be informed of the protections and the limits to protections provided by this Certificate through the informed consent process. All study staff who obtain consent from study subjects will be trained on how the Certificate protects the information collected and the limitations of the Certificate’s protections.

At the beginning of the study, each participant will be assigned a unique identification number. The unique identification number will be used when collecting all questionnaire, cognitive, and physiologic data. The key containing participant names and unique identification numbers will be maintained at the NIOSH Spokane Research Laboratory in a locked file cabinet. NIOSH facilities are secured 24-hours a day. Deidentified data will be stored electronically on secure NIOSH servers. Access to NIOSH servers is possible only through a 2-step authentication system. A third layer of protection will limit access to the secure directory to NIOSH staff authorized to work on this project. NIOSH data servers meet standards

developed by CDC's Office of the Chief Information Security Officer. These standards comply with Federal and HHS policies related to information security (available at <http://intranet.cdc.gov/ociso>). The link between name and unique identification number will be destroyed after all data collection has been completed, and after data have been checked for quality and completeness.

Questionnaire data for both the field and environmental chamber studies will be collected electronically using the Epi Info Secure Web Survey system (EISWS), an ITSO/ISSO Level 2-approved FedRAMP-certified software. This software also already has a PIA certificate. Only study members will be able to access these data.

For the field study, physiologic data (e.g., heart rate, core body temperature) will be collected and stored on smart phone devices. The data will be collected using smart phones with security protections that are applied to securely store participant information. These phones will be without a data plan or cell service, limiting the possibility of data being intercepted during transmission. They will also have customizable passcode-protections that will limit individual access to the research data. Additionally, all personal information provided by the participants will be deidentified using a unique identifier instead of participant names for the entirety of data collection activities. Following each assessment day, participant data will be immediately extracted and transmitted from the devices to an encrypted CDC hard drive using offline USB data transfer on a password protected CDC-issued computer. The data will also be backed up on an encrypted external hard drive. After the data are checked to ensure complete transmission, the data will be wiped from the phones. When investigators return to NIOSH facilities, the data will be transferred over a secure CDC network to CDC servers. Investigators will work with NIOSH ITSO staff and the IRB to ensure that all of the data obtained during this study will be secured, transmitted, and stored in compliance with institutional policies.

For the environmental chamber study, data collection will be performed at the secure NIOSH laboratory in Spokane, WA. Physiologic data will be collected on sensor electronics modules (SEMs) that are directly fixed to each participant's bio-harness. At the end of each study day, participant data will be immediately transferred from the SEM to a password protected CDC computer and placed on secure CDC servers. Data will then be deleted from the recorders. Cognitive testing will occur using CDC laptops, and data will be directly stored on secure CDC servers. The laptops will not leave the NIOSH facility. PII will not be included in data stored on NIOSH servers for either the field or environmental chamber study.

NIOSH will not release any information on individual participants without a signed release. Only aggregated data from this survey will be published. Mine operators will not receive data on individual miners. If aggregated data are provided to mine operators, NIOSH will ensure that the numbers of participating miners are sufficient to prevent re-identification of miners.

11. Justification for Sensitive Questions

The proposed questionnaire contains questions that may be sensitive in nature, including questions regarding chronic diseases (heart disease, diabetes, kidney disease, cancer); use of medications for pain, depression, or anxiety; marijuana use; opinions regarding the emphasis that mine management places on the health and safety of miners; and risk factors for chronic disease such as excessive alcohol use and

tobacco use. Responses to these questions will provide information on risk factors for heat strain, heat illness, or cognitive decline. Additionally, these questions are needed to ensure that participants in the environmental chamber study can safely participate; risk stratification will be based in part on responses to the health questionnaire. For instance, it is important to know if someone has been diagnosed with heart disease or diabetes, because these conditions can increase the risk of adverse events in the environmental chamber. Some medications and drugs or alcohol can affect heat tolerance, the physiologic response to exercise, or cognitive test results, and thus this information must be included. Some sensitive questions are needed to enable investigators in analyzing the burden of heat strain. For instance, kidney disease can result from excessive heat exposure, and obtaining this information could provide insight into the effects of heat strain on kidney disease among miners. Finally, some questions on chronic disease (i.e. respiratory disease) and medication/drug use are needed to allow investigators to correctly interpret physiologic data, because these medications can affect heart rate.

Knowledge of individual miner responses by mine management (for the field study) or by work site managers (for the environmental chamber study) could conceivably damage the employability of these workers. Therefore, all responses will be kept confidential and will not be shared with management. Responses will be aggregated over multiple workers to prevent management from inferring responses from their individual workers.

12. Estimates of Annualized Burden of Hours and Costs

Field

The respondents targeted for this study are underground and surface miners of all sectors. Project staff will recruit 59 miners and the majority will work in areas identified as being at increased risk for heat stress. On the first day, miners will complete an informed consent form (30 minutes), complete an initial health screening questionnaire (30 minutes), and complete a baseline Psychomotor Vigilance Test (PVT) (5 minutes) that is taken by smart phone app. Then, on two separate study days, miners swallow a pill to monitor core body temperature (1 minute each day, a total of 2 times), be fitted with a chest strap to monitor heart rate (1 minute each day, a total of 2 times), complete a mid-shift questionnaire that is taken via smart phone app twice per shift (1 minute for each survey, complete a total of 4 times), complete a PVT that is taken twice per shift (5 minutes for each cognitive test, a total of 4 times), and complete a post-shift questionnaire (10 minutes each day, a total of 2 times).

Data collection will be performed with various data collection instruments and will be collected at the mine site. Pre- and post- shift questionnaires will take place outside of working hours.

The following table provides an estimate of the total burden hours. The estimates are based on 1) the researchers' previous experience conducting similar methods of data collection, and 2) the length of time allotted for cognitive testing.

We do not anticipate a disruption of the miners' normal work schedules as data will be collected for only 12 minutes (two assessments of mid-shift questionnaire + PVT cognitive test) during working hours each testing day.

Chamber

The respondents targeted for this study are local miners (all sectors, both surface and underground), construction workers, and structural and wildland firefighters who are 18-54 years of age. Project staff will recruit 30 participants. Participants will participate over 3 study days.

Day 1: swallow a pill to monitor core body temperature (1 minute), be fitted with a chest strap to monitor heart rate (1 minute), review and sign informed consent form (30 minutes), complete initial health screening questionnaire (30 minutes), undergo initial health exam (10 minutes), complete control exercise session including the thermal sensation scale (TSS) and exertion level using Rated Perceived Exertion (RPE, Borg scale) assessed every 5 minutes (1 minute total), answer Karolinska Sleepiness Scale (KSS) and Positive and Negative Affect Schedule (PANAS) and fatigue pre-cognitive testing (2 minutes total), and take cognitive tests using PVT and N-back (11 minutes total).

Additionally, if the participant is aged ≥ 40 years and/or has diabetes or previously diagnosed kidney disease, they will undergo point-of-care testing with a fingerstick blood sample for further risk stratification (1 minute). If the screening health professional needs additional information from the participant's healthcare provider, the participant will sign a release of information form (1 minute).

Day 2 and Day 3: each day, swallow a pill to monitor core body temperature (1 minute), be fitted with a chest strap to monitor heart rate (1 minute), complete pre-testing health questionnaire (5 minutes) and two rounds of the exercise series with TSS and RPE assessed every 5 minutes (1 minute total). During these two rounds, participants will exercise until their body reaches a certain temperature threshold and will take the KSS, PANAS, and fatigue scales prior to cognitive tests (2 minutes total). Finally, they will take the PVT and N-back cognitive tests (11 minutes total).

Data collection will be performed with various data collection instruments and will be collected at the Spokane Research Laboratory (SRL). We do not anticipate a disruption of the workers' normal work schedules as participants will be scheduled for testing during their off hours.

The following table provides an estimate of the total burden hours. The estimates are based on 1) the researcher's previous experience conducting similar methods of data collection, and 2) the length of time allotted for cognitive testing.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (Hours)	Total Burden (Hours)
Field study					
Miners	Ingestion of temperature pill	30	2	1/60	1
Miners	Fitting of chest strap	30	2	1/60	1
Miners	Consent form (field)	30	1	30/60	15
Miners	Health screening questionnaire (field)	30	1	30/60	15
Miners	Heat stress app – shift questionnaire (field)	30	4	1/60	2
Miners	PVT cognitive test (field) – No form	30	5	5/60	13

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (Hours)	Total Burden (Hours)
Miners	Heat stress app - post-shift questionnaire (field)	30	2	10/60	10
				Total	57
Chamber study					
Miners/ firefighters/ construction workers	Ingestion of temperature pill- No form	15	3	1/60	1
Miners/ firefighters/ construction workers	Fitting of chest strap- No form	15	3	1/60	1
Miners/ firefighters/ construction workers	Consent form (chamber)	15	1	30/60	8
Miners/ firefighters/ construction workers	Physical examination	15	1	10/60	3
Miners/ firefighters/ construction workers	Health screening questionnaire (chamber)	15	1	30/60	8
Miners/ firefighters/ construction workers	Fingerstick blood sample for point-of-care testing -No form	8	1	1/60	1
Miners/ firefighters/ construction workers	Release of Information (HIPPA)	3	1	1/60	1
Miners/ firefighters/ construction workers	Borg and thermal scale	15	5	1/60	2
Miners/ firefighters/ construction workers	PANAS KSS fatigue	15	5	2/60	3

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (Hours)	Total Burden (Hours)
Miners/ firefighters/ construction workers	Cognitive test: PVT (chamber)-No Form	15	5	10/60	13
Miners/ firefighters/ construction workers	Cognitive test: N-back - No form	15	5	1/60	2
Miners/ firefighters/ construction workers	Pre-test screening questionnaire (chamber)	15	2	5/60	3
				Total	46
				Overall Total	103

B

The estimated annualized cost for this information collection is \$2,258.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Median Hourly Wage Rate	Total Respondent Costs
Production mine workers, all sectors	57	\$22.18	\$1,265
Mine worker, firefighter, or construction laborer	46	\$21.58 (avg of 3 occupations)	\$993

This rate was based on the median hourly wage for Mining (except Oil and Gas), Federal Firefighters, and Construction Laborers from Bureau of Labor Statistics, May 2018 National Industry-Specific Occupational Employment and Wage Estimates

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional cost burdens to respondents or record keepers.

14. Annualized Cost to the Government

The time allotted for the project is two years. During this two-year period, participant recruitment, data collection, analysis and presentations are expected to occur. The estimated hourly cost to the Federal Government is \$33.00 per hour for federal government employees and \$150 per hour for contractors. This includes data collection, data analysis, and report writing by CDC/NIOSH employees and

contractors. The hours designated for staff were calculated as shown in the table below. The total cost average for a two-year period is \$452,560.

	Hours	Hourly Rate	Cost at Hourly Rate	Other Costs (data collection, etc.)	Total
Federal Government Employee	4160	\$33.00	\$137,280	\$45,000	\$182,280
Contractor Costs	293	\$150	\$44,000	0	\$44,000

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will begin in 2021 and will occur over the course of approximately 3 years. The project schedules below provide an estimate of data collection activities, analysis, and dissemination. We are requesting OMB clearance for the maximum 3 years because data collection is likely to extend into the third year. Results of these analyses will be published in scientific journals and presented at national public health and mining industry-sponsored conferences.

Activity	Time Schedule
Contact mines for recruitment for field study	During OMB review
Contact mines, construction sites, and firefighters for recruitment for environmental chamber study	During OMB review
Outreach to recruited mines, construction sites, and firefighters to schedule data collection	1-2 months after OMB approval
Data collection	1 month to 1 ½ years after OMB approval
Data cleaning and analysis	6 months to 3 years after approval
Provide reports to participants	6 months to 3 years after approval (on rolling basis after each participant completes data collection)
Publish findings from studies	3 years after OMB approval
Disseminate results to industry	3 years after OMB approval

We will perform a descriptive analysis of the cognitive test results and risk factors for heat strain. We will fit a log-logistic time to event frailty model, which accounts for repeated measures, or generalized linear mixed model, depending on specific cognitive test, to evaluate the effect on cognitive tests of core body temperature. We will also perform time series analyses to evaluate the time to reach certain temperatures. Potential confounding factors will be evaluated in the models and include physiologic

measures, personal factors, and environmental factors. Inclusion of some of the demographic variables will depend on the diversity of the sample population.

To assess patterns of heat strain among U.S. surface and underground miners, only physiologic data from the field will be used. We will use the same methodology described in Yeoman et al. (2019) to categorize core body temperatures into four zones: <37.5, 37.5 to <38, 38 to <38.5, and ≥ 38.5 °C. Core body temperatures during each participant's entire shift will be grouped into zones based on consecutive temperatures within the same temperature zone. We will calculate mean, maximum, and range of number of times participants move from one CBT zone to another, the number of times participants cross the 38 °C threshold, and the mean, maximum, and range of minutes spent in each zone per shift. We will also calculate maximum CBT by self-reported work task.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There is no request for an exception to the certification statement.

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