Appendix K: Informed Consent

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

CENTERS FOR DISEASE CONTROL AND PREVENTION

U.S. PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

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1. DESCRIPTION
2. Title: Informational Needs of Underground Coal Miners
3. Sponsor and/or Project Officer: Jennica Roche, MS
4. Purpose and Benefits: The purpose of this research is to understand what information is needed to complete critical tasks in an underground coal mine. The data will be used to influence future communication and monitoring equipment in mining.
5. CONDITIONS OF THE STUDY
6. **Study Overview**

This experiment is an observational study, focused on the specific tasks, information, and communication necessary to complete critical tasks in an underground coal mine. All activities will take place at your mine site over a single shift. The activities of this study will take approximately **4 hours** of your time and occur during normal working hours. However, the vast majority of the time will be spent with us watching you work and should proceed like a normal day.

**Table 1: Time requirement estimates for each subject**

|  |  |  |
| --- | --- | --- |
| **Description** | **Minimum** | **Maximum** |
| Consent | 2 minutes | 5 minutes |
| Introduction | 2 minutes | 5 minutes |
| Demographic Information | 0 minutes | 5 minutes |
| Observation | 240 minutes | 240 minutes |
| Debrief | 15 minutes | 30 minutes |
| Totals | 259 minutes | 290 minutes |

1. Introduction: We will introduce ourselves, discuss what we would like to observe, and discuss any concerns or limitations.
2. Demographic Information: We will be collecting some basic information about you and your mining experience. This can be collected verbally or written depending on our schedule.
3. Observation: We will meet/follow you underground and observe your work. We ask that you try to proceed through your day like any other. We will have minimal interaction with you, except to ask a question (if it is an appropriate time). While you are working, we may also take pictures periodically and record your voice, as permitted by the mine. At the end of your shift or during any free time you have, we would also like to talk with you for a brief period of time to fill in any missing information from the observation and address any questions that you may have. If you do not wish to be photographed or recorded, you can still participate in the study. Please let one of the researchers know that this is the case, and you will not be required to sign a talent waiver.

Notes will be taken without any identifiers that will link this information directly to you. Every effort will be made to keep your participation confidential.

1. **Risks**
	1. Risk of breach of confidentiality: There is a rare risk of a breach of confidentiality, meaning that information about you collected for the research study may be accessed by people who are not the investigators or the research staff of the investigators associated with the study. We believe the risk is very rare and all possible safety measures will be taken to insure confidentiality.

If you have any questions and/or comments about the study, you should contact:

Jennica Bellanca

Human Factors Branch; NIOSH

(412) 386-6445

Lisa Steiner, Team Leader

Human Factors Branch; NIOSH

(412) 386-6446

1. **Alternative Procedures**

There are no alternative procedures.

1. **Medical**

Injury or harm from this project is unlikely, but if it results, medical care is not provided. If you are injured through negligence of a NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the federal government, your contact point is, General Law Division of OGC; request the Claims Office: (202) 233-0233. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If injury or harm should occur to you as the result of your participation, you also should contact Jennica Bellanca at 412-386-6445 or Mark A. Toraason, Chair, NIOSH Human Subjects Review Board (HSRB), 513-533-8591.

1. **Questions**

If you have questions about this research, contact Jennica Bellanca at 412-386-6445. If you have questions about your rights as a member of this study, contact Mark A. Toraason, Chair, NIOSH HSRB, 513-533-8591.

1. **Voluntary Participation**

Your participation is voluntary, and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

1. **Reimbursement**

A $25 gift card to a local retail store will be provided as reimbursement for your time. If you chose to withdraw, you will receive the $25 gift card if you have completed 50% or more of the study.

1. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, along with your social security number (if applicable), because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting ismaintained and retrieved bypersonal identifiers, such as yourname and social security number, it will become part of the CDC record system and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorizedto release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

1. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this study.

PARTICIPANT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

 (Signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRSENTATIVE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

 (Signature)

Appendix A

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, “Occupational Health Epidemiological Studies and EEOICPA Program Records” and may be disclosed to

* Appropriate state or local health departments to report communicable diseases;
* A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;
* Private contractors assisting NIOSH;
* Collaborating researchers under certain circumstances to conduct further investigations;
* One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;
* The Department of Justice or the Department of Labor in the event of litigation;
* Congressional offices assisting an individual in locating his or her records;

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

Miner Introduction Script

Hello, my name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and I work for National Institute of Occupational Safety and Health - NIOSH. NIOSH is a government research agency that works to improve health and safety and eliminate injuries and illnesses in the workplace. Our division is specifically interested in the issues related to mining. NIOSH is currently doing research on the informational and attentional demands that miners face. This means, we are interested in the things that you looks for, look at, hear, or report that help you do your job better and safer. We are interested in what miners - specifically the fire boss and continuous miner operator - need to know and understand to do their jobs well. You have been referred to us by your mine, because you are experienced and know how to do your job well. We would like to spend a few hours today to observe you work. We are not interested in how fast you perform any of your tasks, just what you do, what you check, and when you do these tasks. I want to stress that your participation is completely voluntary and that you may withdraw at any time. Additionally, you will be reimbursed with a $25 gift certificate to \_\_\_\_\_\_\_\_\_\_\_\_\_\_ for your time and participation. Your data will be treated in a confidential manner, unless otherwise compelled by law. The information you provide will be analyzed and reported along with the information provided by miners at other mines. In any public release of survey results, no data will be disclosed that could be used to identify specific individuals. Only NIOSH staff who are involved in collecting or preparing the information for analysis will have access to your specific answers.

Do you have any questions before we begin?