

APPENDIX L: FIELD EVALUATION 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

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.

I. DESCRIPTION

1. Title: Usability Testing of Commercially Available Mining Vest(s)
2. Sponsor and/or Project Officer: Jennica Roche, MS
3. Purpose and Benefits: The purpose of this research is to collect usability data evaluating the effectiveness of a modified commercially available mining vest made by Ergodyne[®]. Data collected will be used to influence the design of future modular carriage systems.

II. CONDITIONS OF THE STUDY

1. **Study Overview**

This experiment will be evaluating the effectiveness of a modified Ergodyne[®] mining vest during daily operations. All activities will take place at **Roytown Mine** and **Sarah Mine** over a month period. The activities of this study should only take approximately 90 to 140 minutes of your time, and they will be completed during working hours. For this study, you will be given a mining vest to be used during the month, and it will be collected following the completion of the study.

Table 1: Time requirement estimates for each subject

Description	Minimum	Maximum
Consent	5 minutes	5 minutes
Introduction	5 minutes	10 minutes
Vest Fitting	10 minute	15 minutes
Setup Documentation (2x)	5 minutes	5 minutes
Questionnaire (2x)	20 minutes	30 minutes
Weekly Questions (4x)	5 minutes	10 minutes
Totals	90 minutes	140 minutes

- a. Introduction: We will introduce ourselves, demonstrate the functions of the vest, and demonstrate how to wear and size the vest.
- b. Vest Fitting: We will help you size the vest so that it fits you properly and will cause minimal discomfort.
- c. Questionnaire: The questionnaire will be multiple choice and short response questions about yourself, your job, and you opinions on wearing a mining vest. You will be asked

to fill out this questionnaire twice, once at the start of the month and again after you are finished.

- d. Weekly Questions and Diary: You will be given a small notebook with preprinted question and space to record any problems with or benefits of the mining vest. We ask that you please fill it out at the end of every week for all four weeks.

Your data will be collected without any identifiers that will link this information to you. Every effort will be made to keep the information collected from you during these activities confidential.

2. Risks

- a. Risk of Muscle Soreness and Discomfort: There is a minimal risk of minor muscle discomfort. The change in loading from belt-style to vest-style may cause discomfort while performing daily mining tasks. You are encouraged to change your vest setup as needed to minimize discomfort associated with the vest.
- b. Risk of Snagging: There is a minimal risk of snagging the vest on something in the mining environment. However, this risk is not greater than the normal risk while wear any other article of clothing. Full effort has been made to assure your optimal safety by reducing loose fabric on vests and the addition of reflective material.
- c. 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

3. Alternative Procedures

There are no alternative procedures.

4. 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 Roche at 412-386-6445 or Mark A. Toraason, Chair, NIOSH Human Subjects Review Board (HSRB), 513-533-8591.

5. Questions

If you have questions about this research, contact Jennica Roche 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.

6. 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.

7. Reimbursement

No reimbursement or compensation will be provided to you because you will be participating during normal work hours with the approval of management.

III. 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 is maintained and retrieved by personal identifiers, such as your name 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 authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

IV. 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: _____
(Signature)

Date: _____

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

REPRESENTATIVE: _____
(Signature)

Date: _____

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.

INTRODUCTION/CONSENT SCRIPT

Hello, my name is _____, and I work for NIOSH. NIOSH is doing a research study to test the usability of a mining vest. For this research study, we will be giving you a mining vest to try out for a month and see what you think. For the month of the study, you will be able to use the mining vest as best works for you. However, we will then be collecting the vests back at the end of the study to fully evaluate the wear. Please don't be concerned by this; we are simply interested in how the vest holds up during actual use. Additionally, to better understand your needs in a mining vest, we will also be asking you a series of questions about you, your experience, your job, your thoughts, and opinions of a mining vest in general, and your thoughts and opinions of the vest we give you. We will also be taking pictures of how you setup the vest today and how you have it setup a month from now. I want to stress that your participation is completely voluntary and that you may withdraw at any time. Your responses to the questions 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?