Attachment 4

Consent Form for Phase II

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL
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: Field Evaluation of a Prototype Kneel-assist device

2. Sponsor and/or Project Officer:

Jonisha P. Pollard
NIOSH
Office of Mine Safety and Health Research
626 Cochrans Mill Road
PO Box 18070
Pittsburgh, PA 15236-0070
(412) 386-5220

3. Purpose and Benefits: In this study we will be testing kneel-assist devices comprised of a kneepad and a body weight support worn at the ankle. These kneel-assist devices have been designed to reduce the forces, stresses, and moments at the knee when performing your job. The purpose of this study is to determine how well the kneel-assist devices work in a mining environment. The overall goal of this project is to decrease the risk of knee injuries in low-seam mines.

II. CONDITIONS OF THE STUDY

1. *Procedure*

The following procedure will be followed:

1. For completing this interview, you will receive a $25 gift card to either Lowes or The Home Depot, depending on which store is located closest to your community.
2. You will first fill out this consent form. Please feel free to ask the researchers questions at any time. (approximately 15 minutes)
3. The researchers will then ask you a few questions. The researchers will be using a questionnaire as a guide for the interview. These questions will be about the current kneepad you are using. As you answer the questions, the researchers will be writing down your answers. (approximately 30 minutes)
4. Once you have completed the questionnaire, you will be given either a kneepad of your choice or the kneel-assist devices. You will also be given a second pair so that you

may adequately clean your kneel-assist devices/kneepad each night and allow time for them to dry before you use them again.

5. The study will go on for 12 months. At 1, 3, and 6 months following when you received the kneepad of your choice, the researchers will again visit the mine and ask you the same questions they did previously. Throughout the study, you will be given additional pairs of the kneepad of your choice as needed. However, you must only use the kneepads you are given.
6. After the first 6 months, you will be given the kneel-assist devices. The same questionnaire used for the kneepad of your choice will also be used to evaluate the kneel-assist devices at 1, 3, and 6 months. (approximately 30 minutes per interview) Throughout the study, you will be given additional pairs of the kneel-assist devices as needed. However, you must only use the kneel-assist devices you are given.
7. You will receive a reimbursement of $25 for each interview you complete. If you complete the entire study, you will receive a total of $125. If you choose to leave the study early, you will still be reimbursed for the number of interviews you completed.
8. The following actions will be considered "leaving the study early": 1) when evaluating your kneepad of choice, using a kneepad/device other than the ones provided for more than 3 shifts and 2) when evaluating the kneel-assist devices, using a kneepad/device other than the provided kneepad portion of the kneel-assist device for more than 3 shifts. **NOTE: You may choose to not use with body weight support worn at the ankle at any time without it being considered withdrawing from the study.**
9. If you are a section foreman, you will also be asked additional questions about the environmental conditions in the mine (e.g. seam height). You will be asked these questions each month. The researchers will call the mine to go over the questions. No additional reimbursement will be associated with answering these questions. (approximately 10 minutes per interview)
10. You may quit the study at any time, for any reason. You will be reimbursed for the portion of the study you participated in. If you feel you have experienced an injury due to use of the kneel-assist devices or kneepad, please contact NIOSH personnel immediately.

11. Risks and Discomfort

You will only perform your normal job tasks for this study. The kneel-assist device or kneepad are expected to result in only no or minimal discomfort. In the event of any problems/concerns, you should contact:

Joel Haight, PhD
Chief, NIOSH-Human Factors Branch
(412) 386-6648

Jonisha P. Pollard, M.S.
NIOSH-Human Factors Branch
(412) 386-5220

12. No alternative test procedures are available.

13. Injury or harm from this project is unlikely. But if it results, medical care is not provided, other than emergency treatment. 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 an injury or harm should occur to you as the result of your participation, you also should contact:

Jonisha P. Pollard, M.S.
NIOSH-Human Factors Branch
(412) 386-5220

Mark Toraason
Chair, Human Subjects Review Board-Institutional Review Board
NIOSH
(513) 533-8591

14. If you have questions about this research, contact Jonisha Pollard (412) 386-5220. If you have questions about your rights as a member of this research study, contact Mark Toraason, Chair, NIOSH Human Subjects Review Board – Institutional Review Board, 513-533-8591.

15. Your participation is voluntary. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. You will be reimbursed for the portion of the study you completed.

16. The results of this study will be published and made available to you at your request. The publication process may take months or years depending on the type of publication. For a copy of any published results, please contact Jonisha Pollard at 412-386-5220 or via email JPollard@cdc.gov.

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 (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 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_____Age _____
(signature)

(and Guardian, if required)_____Date_____

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

REPRESENTATIVE_____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 heath 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;**
- **The Department of Justice to assist in determining the eligibility for compensation to uranium workers or their survivors [optional but must be used if study pertains to uranium workers]**

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.