Form Approved
OMB No. 0920-XXXX
Exp.Date__xx/xx/20xx__

Attachment G-2:

Informed Consent
(Low Back Functional Assessment)

This informed consent will be completed by a 20% sample of employees who participate in the low back functional assessment at the start of the study.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
Consent for the subset of the study cohort who will be asked to participate in the low back functional assessment

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**: Musculoskeletal disorder (MSD) intervention effectiveness in wholesale/ retail trade operations (Functional Low Back Test)

2: **Sponsor and Project Officers**: This study is being done by the National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio, 45226. The Project Officer is Steve Wurzelbacher, Ph.D.

3: **Purpose and Benefits:**

We want to find out how effective controls like powered hand trucks are in reducing low back and shoulder pain among delivery workers. To determine this, we have already asked you to participate in a questionnaire based health assessment. For a sample of additional employees, we are also asking you participate in a test of your low back function once a year for a 2-year period (a total of three 20-minute tests).

Although there are no immediate direct benefits to you from being in the study, the information gained from the study may help to improve our understanding of how to prevent low back and shoulder disorders. The information may also help design tools, equipment, and practices to improve delivery tasks.

II. CONDITIONS OF THE STUDY

1: **Low back test**

As a participant, you will be asked to complete a questionnaire about your low back pain (same questionnaire used for the other part of the study in which you participated, **Appendix 9).** You will also be asked to complete a functional back assessment. Total time is estimated at 20 minutes. The questionnaire asks about back pain and physical activities. For the assessment of back function, you will be asked to wear a lightweight device on your back and will be asked to bend forward and backward. The device measures motion information which is used to assess back function. Injury or lasting discomfort from these tests is very unlikely.

Altogether, you will be asked to:
i) Complete a 5 minute questionnaire about your low back pain.
ii) Complete a 15 minute assessment of back function.

It is estimated it will require 60 total minutes (three 20-minute tests) of your time for the entire back functional assessment study.

2: There is little risk to you from the back function test. If you have any concerns about the tests, you should contact the NIOSH Project officer, Steve Wurzelbacher, 513-841-4322.

3: No alternative tests are appropriate for this study.

4: Your participation is voluntary and you may withdraw from this study at any time without penalty or loss of benefits that are due to you. <<The following will be added for those workers who participate outside of normal work hours. You will receive $25 for your time and inconvenience.>>

5: Injury 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: Claims Office: (202) 233-0233, General Law Division of the Office of General Council (OGC). If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the

federal government. If an injury should occur to you as the result of your participation, you also should contact either:

Steve Wurzelbacher, Ph.D., Project Officer
National Institute for Occupational Safety and Health
4676 Columbia Parkway, R-14
Cincinnati, OH 45226
(513) 841-4322
srw3@cdc.gov

Mark Toraason, Ph.D., Chairperson, NIOSH HSRB
National Institute for Occupational Safety and Health
4676 Columbia Parkway, C-11
Cincinnati, OH 45226
(513) 533-8207

If you have questions about this study, contact Steve Wurzelbacher at the email addresses and phone numbers listed above. If you have questions about your rights as a member of this study, contact Mark Toraason at the address and phone number above.

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. NIOSH collects 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 such information, including results from this study 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. Personally identifiable information and company information will be protected to the extent allowed by law. There are conditions under the Privacy Act when NIOSH 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 I agree to participate in this study.

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PARTICIPANT_____
(Signature)

Name (first and last name printed)_____ Today's Date:_____

Email Address_____

Address:
Street _____ Phone ( )_____

City_____State_____ Zip_____

Date Of Birth: MONTH_____ DAY_____YEAR_____

Please indicate here whether NIOSH has permission to contact you at the above address, phone number, and email address for the purpose of conducting this study. Yes_____ No _____

I, the NIOSH representative or their agent (contractor), have accurately described this study to the participant:

REPRESENTATIVE:_____ Date:_____
(Signature)

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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.