MUSCULOSKELETAL DISORDER (MSD) INTERVENTION EFFECTIVENESS IN WHOLESALE/ RETAIL TRADE OPERATIONS

Request for Office of Management and Budget (OMB) Review and Approval
for a Federally Sponsored Data Collection

Supporting Statement B

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

For the current study, NIOSH and the Ohio Bureau of Workers Compensation (OBWC) will collaborate on a multi-site intervention study at OBWC-insured wholesale-retail trade (WRT) companies from 2011-2014. In overview, MSD engineering control interventions (stair-climbing, powered hand trucks and powered truck lift gate) will be tested for effectiveness in reducing self-reported back and upper extremity pain among 960 employees performing delivery operations in 72 WRT establishments using a prospective experimental design (multiple baselines across groups with randomization).

B1. Respondent Universe and Sampling Methods

Definitions of the Target Population, Sampling Frame, Study Sample and Sub-Sample

For this study, the target population (people, groups or workplaces which might benefit from the MSD interventions being tested) includes United States WRT establishments [North American Industry Classification System (NAICS) industry codes 42-45] performing delivery operations. The sampling frame (segment of the target population) includes OBWC-insured WRT establishments performing delivery operations. The study sample (people, work groups or workplaces chosen from the sampling frame) includes OBWC-insured WRT establishments who volunteer to participate in this OBWC-NIOSH collaboration research project funded through the existing Safety Grant program. Since the size of the establishment is likely to be an important factor in intervention effectiveness, 24 establishments will be recruited from each of three total employee categories (<20 employees, 20-99 employees, and 100+ employees) for a total of 72 establishments with 3,240 employees. The study sub-sample (people, work groups or workplaces chosen from the sampling frame) will be volunteer employees at OBWC-insured WRT establishments or similar operations who perform material handling tasks related to the delivery operations of large items (such as appliances, furniture, vending machines, furnaces, or water heaters) that are expected to be impacted by the powered hand truck (PHT) and truck lift gate (TLG) interventions. In prior OBWC studies using the PHT-TLG interventions, the ratio of total employees to impacted employees was 5 to 1 and it is estimated that there will be 960 impacted employees (20% of total volunteer establishment employees, plus replacement employees who drop out of the study) in the 72 recruited establishments.

Example tasks expected to be impacted by the PHT-TLG intervention include:

- Material handling of large items (100+ lbs., such as appliances, large electronics equipment) OR stacked smaller items (1-100 lbs. per item, 100+ lbs. per stack)
    - Transfer of new/ returned items from shipper to establishment

- Transfer of new/ returned items within establishment (PHT only)
- Transfer of new/ returned items from establishment to customer residence or vehicle
  - Transfer of load from establishment to delivery vehicle
  - Transfer of load from delivery vehicle to customer residence
- Removal of old/ returned items from customer residence to disposal point
  - Transfer of load from customer residence to delivery vehicle
  - Transfer of load from delivery vehicle to disposal point

Example tasks not-expected to be impacted by the PHT-TLG interventions:

- Material handling of individual smaller items (1-100 lbs.)
- Packing/ unpacking boxes
- Office/ sales- customer service
- Driving

Power Calculations for Main Outcomes

The main outcome of interest for this study will be the North American Spine Society (NASS) Lumbar Spine Outcome Assessment Instrument scores, measured every 3 months. Based on pooled statistics obtained from a study of warehouse workers (Ferguson et al 2008, n=454), the baseline NASS outcome is assumed to have a mean=1.55 (std=0.78). Power calculations are based on a two sample t-test, with equal number of observations in each group. Controlling the type I error at 0.05, and assuming measurements are normally distributed, below are tables of estimated expected differences able to be detected for various standard deviation values. For example, the study sample outlined above (with a total of 384 individuals per intervention; 192 per treatment group) would have adequate power to detect an effect size of .20 or greater if the standard deviation for each group is .7 or less. Daltroy et al 1996 indicated that a NASS scale difference of 0.20 is likely to be clinically significant.

		80% Power				**90% Power**			
		Standard Deviation				Standard Deviation			
		0.6	0.7	0.8	0.9	0.6	0.7	0.8	0.9
	374	0.174	0.203	0.232	0.261	0.202	0.235	0.269	0.302
	384	0.172	0.201	0.229	0.258	0.199	0.232	0.265	0.299
N	394	0.17	0.198	0.226	0.255	0.196	0.229	0.262	0.295
Total	404	0.168	0.196	0.224	0.251	0.194	0.226	0.259	0.291
	414	0.166	0.193	0.221	0.248	0.192	0.224	0.255	0.287
	424	0.164	0.191	0.218	0.245	0.189	0.221	0.252	0.284

The second main outcome of interest for this study will be the Quick DASH and DASH Work outcomes, measured every 3 months. Based on pooled statistics of Hunsaker et al 2002, the baseline DASH outcomes will have the following norms: Total DASH- (mean = 10.10, SD= 14.68, n= 1706) and DASH Work component- (mean = 8.81, SD= 18.37, n= 1610). Controlling the type I error at 0.05, and assuming that pre- and post-intervention measurements are normally distributed, below is an estimated expected differences able to be detected with post intervention n=100.

- Total DASH: detectable mean difference = 4.23 with power=80%, detectable mean difference=4.90 with power=90%
- DASH work component: detectable mean difference= 5.31 with power=80%, detectable mean difference=6.14 with power=90%.

Therefore, the study sample outlined above would have adequate power to detect effect sizes of 7% or more at 90% power. Studies have indicated that the minimal clinically significant difference is a change of 5-7% (Wyrwich et. al. 1999; Redelmeier and Lorig 1993; Beaton et. al. 2001).

B2. Procedures for the Collection of Information

Randomized Multiple Baseline Design

MSD control engineering interventions [a stair-climbing, powered hand truck (PHT) and a powered truck lift gate, (TLG) **Attachment L-1**] will be tested for effectiveness in 72 appliance retail or similar establishments performing delivery operations with 960 employees using a prospective experimental design (multiple baselines across groups with randomization). These interventions were chosen because prior OBWC pilot studies (non-experimental before and after designs) indicated the interventions had a high level of acceptability to target employees, initial high effectiveness in reducing MSD risk factors and potential future MSDs. The sampling strategy and power calculations for this study are provided in B1 above. The costs of the interventions will be funded through existing OBWC Safety Grant funds and participating establishments.

All insured establishments will be stratified by size (i.e., <20, 20-99, 100+ employees) and workers compensation (WC) loss history, and from each stratum 24 establishments (72 in total) will be recruited. Within strata (24 establishments), 12 pairs will be formed according to previous WC loss history. Therefore, the study sample will consist of 36 pairs of establishments with similar WC loss history; 12 pairs of small-size establishments, 12 pairs of mid-size, and 12 pairs of large-size. Within each pair, one establishment will be randomly chosen to receive the PHT or TLG intervention in the first phase, and the other will serve as a matched control until it receives the same intervention 12 months later ("waiting list control"). This study will utilize a multiple time series design known as "multiple baseline design across groups." In this design, both groups eventually receive the intervention, but at different times (**Attachment L-2**). This design may be adjusted to include additional baselines (e.g. every 6 months) to address potential seasonal variations. To clarify, note that the PHT and TLG interventions are

being evaluated separately in two parallel studies, each with 36 establishments and 384 individual participants (480 with replacements).

Independent Variables

There will be three groups of independent variables (Intervention, Individual, and Establishment) described below.

Intervention: The number of interventions (PHTs or TLGs) put into place at each establishment will be proportional to the establishment size and number of expected impacted employees. For example, in prior OBWC studies, the ratio of total employees to impacted employees was 5 to 1, and 1 PHT or TLG was found to be an acceptable level of control for up to 4 impacted employees (those employees expected to use the control in the course of their work). Based on the sampling plan to recruit 24 establishments from each size category, a total of 108 PHTs and 108 TLGs will be required for 960 impacted employees (**Attachment L-2).** OBWC will provide 2:1 matching for these interventions (the same level of match that currently exists in the Safety Grants program). For example, for each $4,000 PHT-TLG, OBWC will pay $2,667 and the participating establishment will pay $1,333. The estimated initial total cost for these interventions is ~$863,784 (108 PHTs and 108 TLGs @$4,000/ intervention, plus replacements if applicable). Participating establishments will also provide regular scheduled maintenance for the PHT-TLG as indicated by the manufacturer. Participating establishments will encourage the use of the PHT-TLG but will not require their use. Target employees will be provided training by participating establishments in the safe use of the PHT-TLG (as outlined by the manufacturer). As part of the Safety Grants program, participating companies are already required to track the man-hours and WC claims of employees impacted by the implemented intervention. This data will be used to calculate intervention-specific MSD rates that will serve as secondary outcomes.

Individual: Two types of individual exposure questionnaires (self-reported general work environment and health, **Attachment H-4** and self-reported specific job tasks and safety incidents, **Attachment H-3**) will be administered to target employees (directly impacted by the PHT-TLG interventions) throughout the course of the study. Each respondent will be assigned a study ID number, and the questionnaire will be identified only with the ID. The list of employee names and ID numbers will be kept separately from the questionnaire data. Participation by individuals is voluntary, and will not be required by participating establishments. If an establishment agrees to participate, but no individuals wish to participate by answering questionnaires, the establishment will still be provided the PHT-TLG intervention and the secondary establishment-level outcomes will be tracked. This protocol will be followed to reduce the chance of establishment coercion for individual participation in order to receive the PHT-TLG. All impacted employees will be recruited by flyers (**Attachment J-4)** placed at each establishment and email to each potential participant by NIOSH. Each participant will be fully informed of the potential risks and benefits of participation and will be asked to complete consent forms. Researchers anticipate no additional risks to participants outside of their typical work duties. Potential benefits could involve reduction in risk for MSDs (associated with

material handling task expected to be impacted by the PHT-TLG). Participants will be given time in their normal work day to complete both exposure assessment and outcomes questionnaires. Participants will be given a $5 debit card upon completion of each combined questionnaire data collection (a total of $45 for the entire study). Participants who complete surveys will also be entered into drawings each quarter to win prizes such as electronic gear. Exposure assessment questionnaires are outlined below:

> **Self-reported general work environment and health** (**Attachment H-4**): Questionnaires will be administered to target employees (directly impacted by the PHT-TLG intervention) at baseline and every 12 months for the study duration to collect self-reported data (28 items) on co-variate health and work conditions.
>
> **Self-reported specific job tasks and safety incidents** (**Attachment H-3**): A second set of questionnaires will be administered to target employees (directly impacted by the PHT-TLG intervention) at baseline and every 3 months (at the same time the MSD symptom surveys are completed). Target employees will be asked to rate the distribution of their workload among tasks expected to be impacted by the PHT-TLG intervention and those tasks where no impact is expected. Employees will also be asked if they have had a safety incident in the last 3 months. In the event that an employee drops out of the study or moves to a non-impacted task, a replacement volunteer employee will be recruited. The same baseline questionnaires described above will be administered to all replacement participating employees. For the employees who left the study (or employment at the establishment), an exit interview will be used to ascertain whether the reason for leaving was MSD-related health problems (**Attachment H-5).** Based on US Census Bureau estimates for mean turnover percentages in the target NAICS codes in Ohio for 2008, this study will expect a turnover in participants of at least 11%.

Low Back Functional Assessment (**Attachment I**): As an additional clinical exposure assessment, a 20% random sample of subjects will be asked to participate in a clinical assessment of their low back function at baseline and at one year follow-up. During this 20 minute test (conducted onsite at the volunteer establishment) subjects will be asked to perform several back motions (e.g. flexion, extension, twisting) to test range-of-motion (ROM). During the tests, the subject will also wear a lumbar motion monitor (LMM), which is used to track the velocity and acceleration of the motions. Other researchers (Marras et al.1999) developed the LMM to compare motion measures to age and gender specific normal values in order to distinguish between healthy and impaired performance as well as benchmark the severity of back injury. The summary ROM values and LMM measures will be compared between control and treatment groups as described below. Participants will be given time in their normal work day to complete the low back functional assessment or will be given a $25 gift certificate if the test is conducted outside of normal work hours.

***Establishment*:** Participating companies will not be restricted from receiving additional OBWC-sponsored services that they would otherwise choose and can freely engage in

other non-OBWC OSH control practices. OBWC already tracks information for establishment usage of OBWC programs and services. This information will be assessed to determine possible history effects. As well, a number of factors external to the establishment will be tracked using publically available sources during the study periods, including changes in state or national legislation (especially those that impact OSH record keeping and the Ohio workers compensation system) and the general business cycle.

Dependent Variables (Outcomes)

Details for the two main outcomes (self-reported low back pain and self-reported upper extremity pain) are provided below and in **Attachment L3.**

Self-reported low back pain (**Attachment H-1)**: The first main outcome will be self-reported low back pain [as measured by the North American Spine Society (NASS) Lumbar Spine Outcome Assessment Instrument], collected at baseline and every 3 months. This instrument has been found to have acceptability, high re-test reliability, internal reliability, and validity for low back pain and disability in multiple language translations (Daltroy et al 1996; Schochat et al 2000; Pose et al 1999; Padua et al 2001; Bosković et al 2009; Schneider et al 2007; Schluessmann et al 2009; Sigl et al 2006; Weigl et al 2006; Schaeren et al 2005). The null hypotheses for this main outcome:

- OIa-1: There will be no difference between mean back Pain & Disability scale score ratios (pre/ post intervention scores) when groups are compared (focusing on time period Baseline A to B)
- OIa-2: Duration of intervention will not be significantly associated with post mean back Pain & Disability scale score declines

Self-reported upper extremity pain (**Attachment H-2**): The second main outcome will be self-reported upper extremity pain (as measured by the Quick DASH Outcome Measure with Work Module Option, Beaton et. al. 2001), collected at baseline and every 3 months. The DASH outcome has been found to have acceptability, high re-test reliability, internal reliability, and validity for upper extremity pain and disability (Beaton et. al. 2001; Hudak et. al. 1996; Adams et. al. 2005; Atroshi et. al. 2000; Gay et. al. 2003). These instruments were jointly developed by IWH and the American Academy of Orthopaedic Surgeons (AAOS) and approved versions are now available in 27 languages. The null hypotheses for this main outcome:

- OIb-1: There will be no difference between mean DASH disability/symptom score ratios (pre/ post intervention scores) when groups are compared (focusing on time period Baseline A to B)
- OIb-2: Duration of intervention will not be significantly associated with post mean DASH disability/symptom score declines

Statistical Analysis

ANOVA tests adjusting for influential individual factors and establishment factors will be used to test the baseline null hypotheses (for example, OIa-1 and OIb-1). A longitudinal mixed effect model will be fit and used to test the OIa-2 and OIb-2 null hypotheses. Participant employees who drop out of the study will be excluded from the main analysis (e.g. for individual employee level MSD Symptoms) and only replacements will be included. The baseline and time points for the replacement measurements will be shifted before any data analysis. All analyses will be conducted using SAS 9.2 (SAS Institute, Inc., Cary, NC).

Study Limitations

Limitations for this study are discussed in **Attachment L-5.**

Recruitment

Firms: OBWC-insured WRT firms will be recruited using an informational flyer (**Attachment J-1**) that is distributed by NIOSH and OBWC. Interested firms will be given additional information including the standard Safety Grants application (**Attachment J-2**) and a detailed description of the voluntary involvement of employees in the study (**Attachment J-3**).

Individuals: Once a firm has agreed to participate, NIOSH will begin recruiting individuals at each firm using informational flyers (**Attachment J-4**) posted at the work site and included in firm and / or union newspapers. Participating firms will also be asked to provide a contact list for individuals performing delivery operations. NIOSH will email the flyer directly to prospective recruits or call recruits if no email address is available. During the phone call, NIOSH will read from the flyer as a script. NIOSH will also visit a sampling of participating firms to meet prospective recruits in person and explain the nature of the study.

Number of Study Participants

Questionnaire Data Collection: A maximum of 960 individuals may be included in the overall questionnaire study for both interventions. This includes 384 individuals per intervention and a 25% uncertainty factor for second-year replacement firms/individuals. It is estimated that 75% of participants will be male based on expected demographics for delivery operations of large items.

Low Back Assessment Data Collection: A maximum of 192 individuals (a subset of the 960 who may participate in the overall study) may be included in the overall questionnaire study. This includes 77 individuals per intervention and a 25% uncertainty factor for second-year replacement firms/individuals.

Data Management, Security and Confidentiality

The study will collect both sensitive data (self-reported MSD symptoms and results from low back functional assessments) and personal identifiers (name, address, phone number, employee clock number). All data will be maintained such that it is identified with an assigned number, and stored in locked file cabinets and on secured computers, accessible only by password. The identification sheets and consent forms will be kept separate in locked file cabinets and will be available only to authorized NIOSH and contractor personnel.

Questionnaires will be administered using several options (self-administered secure web portal, self-administered hard copy forms, and telephonic interviews). The respondent will be strongly encouraged to use the self-administered web-based format of the survey. For those respondents lacking internet connections or those who do not wish to complete a web-based survey, a hard copy format will next be offered. An interview option will be offered as a last resort for those respondents who do not find the web-based or hard copy formats acceptable. The online survey design will comply with applicable 508 requirements (http://www.hhs.gov/od/508policy) to accommodate individuals with disabilities.

A limited amount of digital video may be collected at participant sites to document the types of tasks being conducted pre and post intervention. This video data will not be linked back to any individual participant data. All video data will be kept confidential and managed in accordance with the Privacy Act. To ensure participants' privacy, the only identification in the video databases will be a NIOSH assigned participant company code and task code. The code identifiers will be kept in a secure location in the principal investigators' office. Videos will be saved on a NIOSH computer network that is only accessible by the principal investigator, study co-investigators, and some supporting staff for the study. The participating companies will not have access to the videos. Prior to the video data collection, participants will be verbally asked for permission to video, and uses of participants' video data will be explained to them (**Attachment G-3).** A waiver of written consent is requested for this video permission form to reduce the amount of personally identifiable information collected. The digital video data saved on the NIOSH network will be transferred to DVD discs and saved in a file cabinet located in the principal investigator's office. The principal investigator and study co-investigators may use the video data for designing future interventions or understanding material handling tasks in the WRT sector.

The security of all data collected will be protected to the extent legally possible, as covered by the Privacy Act of 1974, Title 5, United States Code, Section 522 (a). The method of handling the information complies with the Freedom of Information Act and the Privacy Act of 1974. Disclosure under the Privacy Act System is permitted: to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to the Department of Justice in the event of litigation; and to a congressional office assisting individuals in obtaining their records. Records management practices will adhere to all applicable federal, Health and Human Services (HHS), Centers for Disease Control (CDC), and NIOSH IT security policies and procedures [Security Requirements for Federal Information Technology Resources,

January 2010; Health and Human Services Acquisition Regulation (HHSAR), Clause 352.239-72]. For example, data will be stored on encrypted CDs, flash drives, and/or ftp sites according to applicable Federal Information Processing Standards Publications (FIPS PUBS, see http://www.itl.nist.gov/fipspubs).

Use of Results

Results of the study (in de-identified and aggregated form) will be disseminated in the scientific literature and in educational materials through NIOSH and OBWC channels (website, publications).

Notification

Upon completion of the study, an overall summary report of the de-identified and aggregated results will be sent to participating companies and unions. De-identified and aggregated results of the study will also be disseminated in the scientific literature and in educational materials directed at workers to make them more aware of potential MSD interventions. Individual study participants may also choose to receive a summary of their results.

If study participants leave their jobs during the study period, attempts will be made to contact them in order to determine whether those who leave the study are more or less likely to experience musculoskeletal disorders (MSDs). Participants who leave a study job but are still employed at the same worksite will be contacted in person; if they are no longer employed at the study worksite, they will be contacted by telephone. The telephone interview script (**Attachment H-5)** includes an explanation that the interview is voluntary and confidential.

Risks and Benefits

The study presents minimal risks to participants beyond those encountered during their daily work. In reference to vulnerable populations, pregnant women may be among participants. Children (under 18 years) will not be allowed to be participants.

Interventions: Injury/illness statistics are not available for the targeted task of delivery of large loads within WRT operations. However, WRT companies (such as home furnishing stores, NAICS 44229) performing such delivery operations have relatively higher rates of cases with days away from work or restricted duty (DAW) involving overexertion, slip/ trip/falls, and struck by objects than other WRT sub sectors (BLS 2009). The targeted interventions (powered hand truck, PHT and truck lift gate, TLG) are not expected to increase risk of injury/ illness beyond risks to participants beyond those encountered during their daily work. For example, both interventions (PHT-TLG) have been used in prior OBWC-sponsored Safety Grant studies without reported adverse effect or worker injury/ illness that was due to the intervention itself. Participating companies will be expected to follow vendor safety guidelines for the interventions and train employees on the proper use of the equipment to minimize risks. The potential benefits of these

interventions may include reduced manual lifting and push/pull force, reduced awkward postures and reduced safety risk while performing material handling of large loads to/from delivery vehicles and to/from warehouse or delivery site destinations.

Questionnaires: No individuals or participant firms will be identified in published materials. No individuals or participant firms will receive any benefits directly related to participation in the data collection. An overall indirect benefit is that the information gained from the study may help to improve understanding of how to prevent low back and upper extremity disorders. The information may also help design tools, equipment, and practices to improve delivery tasks. Participants will be given a $5 debit card upon completion of each combined questionnaire data collection (a total of $45 for the entire study).

Low Back Functional Assessment: A subset of 77 workers (20% sample) will be asked to participate in a low back functional assessment, which has been administered to both workers and also back disorder patients (Marras et al.,1990, 1993, 1994, 1995, 1995b). Some workers who participate in the low back functional assessment may experience some discomfort, but the discomfort should not be worse than levels experienced during the course of daily work (NIOSH informal communication with Susan Ferguson, PhD, Ohio State University, who has run the test on approximately 1000 subjects). Participants are instructed that they are in control of the test, and are advised to only flex and extend the trunk in a comfortable level of exertion. Study participants will be advised that they may discontinue testing at any time. No payments are expected to be made to participants in those circumstances in which the employer permits all data collection to occur during normal work hours. Participants who participate outside of normal working hours (in the low back functional assessment) will be reimbursed. Each worker will receive a $25 gift certificate to reimburse him/her for their time and travel costs to participate in the study (low back functional assessment). The indirect benefits to the individual and company participants will include information on workplace controls for musculoskeletal disorders. What is learned from this study, when combined with the knowledge gained from other studies, may benefit workers by helping identify best practices and evidence-based controls that reduce the level of physical demands associated with manual material handling.

Informed Consent

Participation in this NIOSH study is completely voluntary and involves minimal risks. The informed consent forms (Overall Study and Questionnaire Data Collection, **Attachment G-1** and Low Back Functional Assessment, **Attachment G-2**) describe the potential benefits and risks of participation in the study. The grade level for the consent process has been estimated to be the 14th grade based on the Simple Measure of Gobbledygook (SMOG) formula (McLaughlin, 1969). This is consistent with the likely estimated grade level of the target respondents for this questionnaire study. Consent forms may be completed online or by using paper forms that will be returned to NIOSH. A waiver of written consent is requested for those individuals who complete and sign consent online (by checking a box that indicates consent next to the participant's typed

name). As mentioned, a waiver of written consent is also requested for the video permission form to reduce the amount of personally identifiable information collected.

Emergency Procedures

This study will involve minimal risks beyond those that occur within the participant's current work duties. In the event that an emergency develops during a study participant's involvement in the research, whether or not it is related to the research, emergency procedures for individual and facility wide incidents consistent with the Occupational Safety and Health Administration (OSHA) requirements as outlined by 1910.120(p)(8) and 1910.120(q)(1-8) will be followed.

Timeline

This study will be conducted over four years.

- **Year 1 (2011):** An Information Collection Request (ICR) will be submitted to the Office of Management and Budget (OMB). Volunteer OBWC-insured WRT establishments will be recruited to participate in onsite MSD intervention studies

- **Year 2 (2012):** The MSD interventions will be placed in Group A establishments. Exposure and outcome surveys (individual and establishment level) for Group A/B establishments will be collected. A 20% sample of individuals will complete low back functional tests.

- **Year 3 (2013):** The MSD interventions will be placed in Group B establishments. Exposure and outcome surveys (individual and establishment level) for Group A/B establishments will be collected. A 20% sample of individuals will complete low back functional tests.

- **Year 4 (2014):** The analysis of study data will be completed to determine the effectiveness of multi-site MSD intervention at OBWC WRT establishments.

B3. Methods to Maximize Response Rates and Deal with Nonresponse

Methods to Maximize Response Rate

This study is designed such that individual participants complete surveys every 3 months for a 2 year period. Several methods (described below) will be utilized to maximize response rate.

Online Surveys: In order to maximize efficiency and reduce burden, a web-based survey is proposed for the majority (estimated 95%) of all data collection. Web-based surveys have gained increasing acceptance as a research tool as they offer many advantages, including:

- On-line surveys create efficiencies because respondents complete them during a much shorter window of time than other survey modes, and at a substantially reduced cost

- On-line surveys create time efficiencies (i.e., less time to complete the survey because it can be programmed to efficiently guide respondents through skip patterns so that they are not asked questions that do not apply to them or have to spend time navigating through complex instructions);

- Respondents potentially have the option of answering questions in a private setting where they feel comfortable and at ease (e.g., at home);

- Respondents can complete the survey within their own time schedule, and can exit the survey at any time and resume the survey where they ended;

- Previous research (Catalano et al 2006) suggests that workers in some industries prefer completing an online survey when given a choice between a web survey and a paper survey.

Brief Survey: Surveys have been designed to be as brief as possible. Baseline time burden is estimated to be 25 minutes while the time burden every 3 months is estimated to be 15 minutes. It is estimated that the total time burden for each participant to complete online surveys over the course of the 2 year survey study is less than 3 hours.

Focused Recruitment: NIOSH will work closely with the OBWC to recruit WRT firms using an informational flyer (**Attachment J-1**). Based on a the past popularity of sponsored OBWC grants for the interventions being tested (powered hand truck and truck lift gate) and given that OBWC is paying 67% of the cost of the interventions, it is anticipated that a sufficient number of establishments will be recruited. NIOSH will then work closely with the participating firms to explain the purpose and importance of the study. NIOSH will begin recruiting individuals at each firm using informational flyers (**Attachment J-4**) posted at the work site and included in firm and / or union newspapers. Participating firms will also be asked to provide a contact list for individuals performing delivery operations. NIOSH will email the flyer directly to prospective recruits or call recruits if no email address is available. NIOSH will also visit a sampling of participating firms to meet prospective recruits in person and explain the nature of the study. It is anticipated that such focused recruitment, a committed participant pool will be established and this will help maximize response rates once the study is underway.

Incentives: Participants will be given a $5 cash card (useable anywhere that accepts major credit cards) upon completion of each combined questionnaire data collection (a total of $45 for the entire study). Participants who complete surveys will also be entered into drawings each quarter to win prizes such as electronic gear. It has been demonstrated that incentives increase participation and reduce non-response bias among study participants [Dillman 1996, as reported by Shettle and Mooney 1999]. Belman et al. [2005] offered a monetary incentive of $20 for participation in their study, achieving a

70% participation rate. Comments received during focus groups with OBWC staff and other stakeholders indicated that incentives would encourage delivery personnel to participate in this study.

Email/ phone call prompts to complete surveys: If the participant gives permission, participants will be sent email or phone call prompts to complete questionnaires. If no response is returned within 1 week of the scheduled data collection date, a second email or phone call prompt will be sent. If no response is returned within 3 weeks of the scheduled data collection date, a third email or phone call prompt will be sent. If no response is returned within 4 weeks of the scheduled data collection date, a fourth email or phone call prompt will be sent to the participant to inquire whether they wish to withdraw from the study. The email and phone script for quarterly prompts will be as follows:

"You are participating in a CDC-NIOSH study. Your next scheduled data collection is now due. Please submit your completed survey XX within XX days. If you have any questions about your participation, contact NIOSH at XX."

Methods To Deal With Non-Response

Once an individual has agreed to participate, continued response rates in excess of 80% are expected for this MSD intervention study. The anticipated most likely reason why an individual will not continue to participate is that they have left employment with the participating firm. Based on US Census Bureau estimates for mean turnover percentages in the target NAICS codes in Ohio for 2008, this study will expect a turnover in participants of at least 11%.

As described above, if no response is returned within 4 weeks of the scheduled data collection date, a fourth email or phone call prompt will be sent to the participant to inquire whether they wish to withdraw from the study. If a participant misses 2 consecutive scheduled quarterly data collections, it will be considered that the individual has left the study. For participants who leave the study for any reasons, an exit interview will be used to ascertain whether the reason for leaving was MSD-related health problems (**Attachment H-5**). Replacement participants will be recruited from the same firm if feasible or from a similar firm in the same treatment group (Group A receiving the interventions in the first 6 months, or Group B receiving the interventions in the second 6 months).

For statistical analyses, participant employees who drop out of the study will be excluded from the main analysis (e.g. for individual employee level MSD Symptoms) and only replacements will be included. The baseline and time points for the replacement measurements will be shifted before any data analysis. Overall survey data will also be analyzed for consistency of response between participants. For example, participants may miss multiple data collections but can continue to participate as long as they do not miss 2 consecutive scheduled quarterly data collections.

B4. Tests of Procedures or Methods to be Undertaken

Data Collection Forms

Estimates of time burden and usability for all data collection forms are based on recent pilot testing conducted at NIOSH and on prior studies that developed, validated, and utilized the collection forms extensively.

Primary Questionnaires (administered to all 960 participants at baseline and every 3 months for 2 years; 15 minutes estimated time for all primary questionnaires combined per data collection):

- Self-reported low back pain: The first main outcome will be self-reported low back pain, as measured by the North American Spine Society (NASS) Lumbar Spine Outcome Assessment Instrument (17 items; estimated time burden is 5 minutes per data collection; **Attachment H-1**). This instrument has been found to have acceptability, high re-test reliability, internal reliability, and validity for low back pain and disability in multiple language translations (Daltroy et al 1996; Schochat et al 2000; Pose et al 1999; Padua et al 2001; Bosković et al 2009; Schneider et al 2007; Schluessmann et al 2009; Sigl et al 2006; Weigl et al 2006; Schaeren et al 2005). This instrument was used in a past NIOSH study that was granted OMB clearance (0920-0551, expiration date 5/31/2005). During recent pilot testing at NIOSH, the average time burden for the "Self-reported low back pain" form was approximately 5 minutes.

- Self-reported upper extremity pain: The second main outcome will be self-reported upper extremity pain, as measured by the Quick DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire (16 items; estimated time burden is 5 minutes per data collection; **Attachment H-2**). The DASH outcome has been found to have acceptability, high re-test reliability, internal reliability, and validity for upper extremity pain and disability (Beaton et. al. 2001; Hudak et. al. 1996; Adams et. al. 2005; Atroshi et. al. 2000; Gay et. al. 2003). These instruments were jointly developed by the Institute for Work and Health (IWH) and the American Academy of Orthopaedic Surgeons (AAOS) and approved versions are now available in 27 languages. During recent pilot testing at NIOSH, the average time burden for the "Self-reported upper extremity" form was approximately 5 minutes.

- Self-reported specific job tasks and safety incidents: This questionnaire will collect exposure information regarding specific tasks related to the use of the intervention and safety incidents (20 items; estimated time burden is 5 minutes per data collection; **Attachment H-3**). This questionnaire was designed by NIOSH specifically for the proposed MSD study. During recent

pilot testing at NIOSH, the average time burden for the "Self-reported specific job tasks and safety incidents" form was approximately 5 minutes.

Secondary Questionnaires

- Self-reported general work environment and health: This questionnaire will collect covariate exposure information related to overall work conditions, health, and behaviors (28 items, administered to all 960 participants at baseline and every 12 months for 2 years; 10 minutes estimated time combined per data collection) (**Attachment H-4).** This questionnaire is a subset of an instrument that was used in a past NIOSH study that was granted OMB clearance (0920-0551, expiration date 5/31/2005). During recent pilot testing at NIOSH, the average time burden for the "Self-reported general work environment and health" form was approximately 10 minutes.

Clinical Examination (administered to a 20% sample of participants at baseline and every 12 months for 2 years; 20 minutes total required time per data collection):

- Low Back Functional Assessment: This is a test conducted onsite (e.g. by a physical therapist) at the volunteer establishment, in which participants will be asked to perform several functions (e.g. back movements) to test range-of-motion (ROM) and current back pain (**Attachment I**). During the tests, the subject will also wear a lumbar motion monitor (LMM), which is used to track the velocity and acceleration of the motions. Other researchers (Marras et al.1999) developed the LMM to compare motion measures to age and gender specific normal values in order to distinguish between healthy and impaired performance as well as benchmark the severity of back injury. Biomechanically, trunk motion performance is expected to decrease as tasks become more asymmetric because smaller oblique muscles are recruited and necessary for motor control during these tasks. The theory suggests that those with healthy low backs would have a different muscle recruitment pattern since different levels of co-contraction would be expected and reflected in a different motion signature compared to those with low back pain. These motion measures are then compared to age and gender specific normal values to distinguish between healthy and impaired performance as well as benchmark the severity of injury. The repeatability and reliability of these measures has been reported previously and found to be excellent (Marras et al, 1999). This low back assessment measure was also used in a past NIOSH study that was granted OMB clearance (0920-0551, expiration date 5/31/2005). During this prior NIOSH study, the average time burden for the functional test and self-reported back pain survey **Attachment H-1**) was approximately 20 minutes.

B5. Individuals Consulted on Statistical Aspects and/or Analyzing Data

NIOSH personnel will primarily design the data collection, will perform the data collection, and analyze the data. It is anticipated that contracted secondary support staff (to be determined) will also aid NIOSH in these data collection tasks. Below is a summary of individual NIOSH staff roles on this project.

Name	Job Title	Division	Contact Information	Roles on Project
Steve Wurzelbacher, Ph.D.	Research Industrial Hygienist	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	Srw3@cdc.gov 513.841.4322	Project Officer: Designed data collection, will collect data, and analyze data
Steve Bertke, Ph.D.	Statistician	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	inh4@cdc.gov 513.841.4493	Designed data collection and will analyze data
Kaori Fujishiro, Ph.D	Epidemiologist / Statistician	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	fnd3@cdc.gov 513.841.4120	Designed data collection and will analyze data
Alysha Meyers, Ph.D.	Epidemiologist	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	itm4@cdc.gov 513.841.4208	Will collect data and analyze data

The Ohio of Bureau of Workers Compensation (OBWC) also helped design the data collection. Below is a summary of individual OBWC staff roles on this project

Name	Job Title	Division	Contact Information	Roles on Project
Mike Lampl, M.S.	Ergonomics Technical Advisor	Division of Safety and Health	Michael.L.1@bwc.state.oh.us 614.995.1203	Designed data collection

Abe Tarawneh, Ph.D.	Superintendent	Division of Safety and Health	Ibraheem.A.1@bwc.state.oh.us 614.466.0384	Supervising OBWC role on overall project

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industry and selected events or exposures leading to injury or illness, 2006.

Bureau of Labor Statistics. 2007. TABLE R8. Incidence rates1 for nonfatal occupational injuries and illnesses involving days away from work2 per 10,000 full-time workers by industry and selected events or exposures leading to injury or illness, 2006.

Bureau of Labor Statistics. 2009. TABLE 3. Hourly mean wage rates by industry and occupational group, May 2009

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