

MUSCULOSKELETAL DISORDER (MSD) INTERVENTION EFFECTIVENESS IN  
AN INSURER-SUPPORTED ENGINEERING CONTROL PROGRAM

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

Supporting Statement B

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## 1B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This is a revision of an information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). This data collection is authorized by Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C. 669) (**Attachment A**). The 60-day Notice for this collection was published in the Federal Register on June 4, 2014, as required by 5 CFR 1320.8(d) (**Attachment B** and <http://www.gpo.gov/fdsys/pkg/FR-2014-06-04/pdf/2014-12838.pdf>).

NIOSH and the Ohio Bureau of Workers Compensation (OBWC) have been collaborating on a multi-site intervention study at OBWC-insured companies from 2011–2014. In overview, MSD engineering control interventions are being tested for effectiveness in reducing self-reported back and upper extremity pain among employees performing manual material handling (MMH) operations. The costs of the interventions are funded through existing OBWC funds and participating establishments. The study sub-sample are volunteer employees at OBWC-insured establishments who perform material and patient handling tasks that are expected to be impacted by the engineering control interventions.

NIOSH proposes a 2 year data collection revision for this study. This revision will allow the previously approved data collection to be completed on currently participating employers/ employees (using the previously approved protocol) and allow new employers/ employees to be enrolled (using a modified protocol).

### **Requested Renewal of the Previously Approved Protocol**

The original protocol has been using a randomized control design where companies were matched based on similarity of tasks, prior loss history, and affected number of employees prior to the intervention being into place. One of the matched pair was then chosen to receive the intervention immediately, while the other company received the intervention 6 months later. As of 1/15/15, a total of 33 companies with 527 affected employees have received intervention grants using this original protocol. Of the affected employees, 103 are currently enrolled and answering surveys, 270 have not responded to consent form requests, 124 consented and then withdrew, 17 left the involved companies before consenting, and 13 declined enrollment. To complete the data collection on these currently enrolled employers/employees using the original protocol, 292 remaining surveys need to be completed, which will require ~21 additional months. See the status table below.

Stage of Completion	Count of Participants	% of Total	Number of Surveys Remaining per Category	Remaining Total surveys	Months to Complete
9th survey completed	16	16%	0	0	3
8th survey completed	9	9%	1	9	3
7th survey completed	17	17%	2	34	3
6th survey completed	17	17%	3	51	3
5th survey completed	25	24%	4	100	3
4th survey completed	16	16%	5	80	3
3rd survey completed	3	3%	6	18	3
<b>TOTAL</b>	<b>103</b>	<b>100%</b>	n/a	<b>292</b>	<b>21</b>

The level of participation among eligible employees within recruited companies is lower than anticipated in the original protocol. The overall response rate among eligible employee is currently 20%. This has been due to a greater than anticipated drop-out rate. Originally, a total of 228 consented (47% participation rate) but subsequently 125 dropped out. Some of this may have been due to difficulty in using the online survey system, which could only be used via full size personal computers or laptops and not smartphones or tablets. Also, the general study design to collect 9 surveys may have fatigued participants and the \$5 incentive may not have been sufficient.

The lower recruitment of companies was due to an expansion of the OBWC intervention program inadvertently removed some incentives to participate in the current NIOSH study. Previously, employers were encouraged to participate in the NIOSH study because they could get funding for certain types of equipment (including many material handling devices such as lift gates and powered hand trucks etc.) that were previously restricted. However, OBWC released restrictions on the types of equipment that could be funded and OBWC consultants received feedback that employers would no longer be willing to wait an additional 6 months to receive equipment..

Although participation is lower than anticipated in the original protocol, the study still represents one of the largest randomized control trial (RCT) studies of this type to measure the effectiveness of a MSD control with both reported symptoms and workers' compensation claims. For this reason, it is requested that we be allowed to continue to collect the symptom data on remaining willing participants. It is hoped that the main research questions can still be answered due to increased expected effect size, as evidenced by a recent NIOSH study. For example, our research group just published a study on the OBWC Safety Intervention Grant that found that the program significantly reduced affected employee claims and costs. For affected employees, total WC claim frequency rates (both medical-only and lost time claims) decreased 66%, lost-time WC claim frequency rates decreased 78%, WC paid cost per employee decreased 81%, and WC geometric mean paid claim cost decreased 30% post-intervention. See the study for more information at <http://www.ncbi.nlm.nih.gov/pubmed/25223846>.

## **Requested Approval of a Revised Protocol Moving Forward**

In part due to the NIOSH study of program effectiveness, the OBWC quadrupled the annual budget for Safety Intervention Grant. In this past year alone (2014), the program provided \$15 million to 535 employers and OBWC allocated an additional \$45 million for fiscal years 2015-17.

Although the program has been shown to effectively reduce workers' compensation claims and costs, it is still unknown how employee symptoms are impacted. Therefore, as part of this new expansion, OBWC asked NIOSH to continue to measure the effectiveness of the program in terms of employee symptoms and other detailed measures. The new expansion gives the opportunity to increase the generalizability of study findings to a greater variety of industries, including health care, and tasks, including patient handling (PH).

For this reason, NIOSH is also requesting approval of a revised protocol moving forward to allow new employers and employees to be enrolled as described below. These changes do not represent an increase in the sample size or burden hours that were originally requested. This protocol is changed from the previous data collection in that:

- A Low Back Functional Assessment is no longer being conducted to increase data collection efficiency. This was only a minor part of the original protocol and other research has already demonstrated the association between reported symptoms and low back functional assessments.
- The study population now includes workers performing material handling tasks in all industries, not just wholesale retail trade. Tested interventions also include a number of material handling engineering controls. These changes were made to increase generalizability of results. The companies will still be matched based on the similarity of tasks for which interventions are being put into place. OBWC specifically requested that other material handling tasks be included to measure the effectiveness of the expanded intervention program in reducing symptoms in a wider variety of industries.
- All employers will now receive the intervention immediately, rather than half being randomly selected to receive the intervention six months later. This change was made to increase participation among employers. The study design still involves collecting symptoms at baseline before the intervention and after the intervention is put into place. The analysis for the revised protocol (before and after intervention study without randomization) will be conducted separately from the 33 employers with the original protocol (before and after intervention study with randomization).

This change is necessary because the expansion of the OHBWC intervention program inadvertently removed some incentives to participate in the current

NIOSH study. Previously, employers were encouraged to participate in the NIOSH study because they could get funding for certain types of equipment (including many material handling devices such as lift gates and powered hand trucks etc.) that were previously restricted. However, OBWC released restrictions on the types of equipment that could be funded and OBWC consultants received feedback that employers would no longer be willing to wait an additional 6 months to receive equipment. This change to remove the waiting period is expected to increase the sample size dramatically since any employer applying for material handling equipment may be eligible. For example, 535 employers received equipment last year (in 2014) and the majority of these involved some material handling interventions.

**The remainder of this document refers solely to the revised new data collection being requested.**

#### 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 MMH/PH establishments. The sampling frame (segment of the target population) includes OBWC-insured MMH/PH establishments. The study sample (people, work groups or workplaces chosen from the sampling frame) includes OBWC-insured MMH/PH establishments who volunteer to participate in this OBWC-NIOSH collaboration research project funded through the existing Safety Grant program. The study sub-sample (people, work groups or workplaces chosen from the sampling frame) are volunteer employees at OBWC-insured MMH/PH establishments or similar operations who perform material handling tasks related to the delivery operations of large single- or multiple-stacked items (such as appliances, furniture, vending machines, furnaces, or water heaters) that are expected to be impacted by the material handling interventions. In prior OBWC studies using material handling interventions, the ratio of total employees to impacted employees was 5 to 1 and it is estimated that there will be up to 200 impacted employees (20% of total volunteer establishment employees, plus replacement employees who drop out of the study) in the 15 recruited establishments.

Example tasks expected to be impacted by the material handling interventions 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

- o 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
- o 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
  
- o Material handling of individual smaller items (1-100 lbs.)
- o Packing/ unpacking boxes
  
- Patient handling
  - o Transfer of patients to/from bed, chair, and/or vehicle

Example tasks not-expected to be impacted by the material handling interventions:

- Office/sales- customer service
- Driving

#### Power Calculations for Main Outcomes

The main outcome of interest for this study is 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 (192 per treatment group with the same group being used pre- and post-intervention) 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.

The second main outcome of interest for this study is 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 has 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

### Multiple Baseline Design

MSD control engineering interventions [such as stair-climbing, powered hand trucks (PHT) or powered truck lift gates (TLG), etc., **Attachment L-1**] are being tested for effectiveness in up to 30 establishments performing MMH/PH operations with up to 200 employees using a prospective design (multiple baselines across groups). These interventions were chosen because prior OBWC pilot studies 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 are being funded through existing OBWC Safety Grant funds and participating establishments. This study utilizes a multiple time series design known as “multiple baseline design across groups.” In this design, all establishments eventually receive interventions, but at different times.

### Independent Variables

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

**Intervention:** The number of interventions put into place at each establishment is 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 MMH intervention 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, a total of 23 interventions are required for 200 impacted employees. OBWC provides 3:1 matching for these interventions (the same level of match that currently exists in the Safety Grants program). Participating establishments also provide regular scheduled maintenance for the intervention as indicated by the manufacturer. Participating establishments encourage the use of the intervention but do not require their use. Target employees are provided training by participating establishments in the safe use of the intervention (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. These data are used to calculate intervention-specific MSD rates that 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**) are being administered to target employees (directly impacted by the interventions) throughout the course of the study. Each respondent is assigned a study ID number, and the questionnaire is identified only with the ID. The list of employee names and ID numbers is kept separately from the questionnaire data. Participation by individuals is voluntary, and is not required by participating establishments. If an establishment agrees to participate, but no individuals wish to participate by answering questionnaires, the establishment is still provided the intervention and the secondary establishment-level outcomes is tracked. This protocol is followed to reduce the chance of establishment coercion for individual participation in order to receive the intervention. All impacted employees are recruited by flyers (**Attachment J-4**) placed at each establishment and email to each potential participant by NIOSH. Each participant is fully informed of the potential risks and benefits of participation and is 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 intervention). Participants are given time in their normal work day to complete both exposure assessment and outcomes questionnaires. Participants are given a \$5 gas card upon completion of each combined questionnaire data collection (a total of \$45 for the entire study). Exposure assessment questionnaires are outlined below:

**Self-reported general work environment and health (Attachment H-4):**

Questionnaires are administered to target employees (directly impacted by the 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 are administered to target employees (directly impacted by the intervention) at baseline and every 3 months (at the same time the MSD symptom surveys are completed). Target employees are asked to rate the distribution of their workload among tasks expected to be impacted by the intervention and those tasks where no impact is expected. Employees are 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 is recruited. The same baseline questionnaires described above are administered to all replacement participating employees. For the employees who leave the study (or employment at the establishment), an exit interview is 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 expects a turnover in participants of at least 11%.

**Establishment:** Participating companies are not 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 are 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 L-3**.

**Self-reported low back pain (Attachment H-1):** The first main outcome is 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
- 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 is 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
- 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 MMH/PH firms are recruited using an informational flyer similar to those used in the original protocol (**Attachment J-1**) distributed by NIOSH and OBWC. Interested firms are 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 recruits 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 are asked to provide a contact list for individuals performing delivery operations. NIOSH emails the flyer directly to prospective recruits or call recruits if no email address is available. During the phone call, NIOSH reads from the flyer as a script. NIOSH may 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 200 individuals may be included in the overall questionnaire study for both interventions. This includes 192 individuals per intervention and an uncertainty factor for second-year replacement firms/individuals. It is estimated that 75% of participants will be male based on expected demographics for material handling operations.

### Data Management, Security and Confidentiality

The study collects both sensitive data (self-reported MSD symptoms) and personal identifiers (name, address, phone number, employee clock number). All data are maintained such that surveys are 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 are kept separate in locked file cabinets and are available only to authorized NIOSH and contractor personnel.

Questionnaires are administered using several options (self-administered secure web portal, self-administered hard copy forms, and telephonic interviews). The respondents

are 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 is next offered. An interview option is offered as a last resort for those respondents who do not find the web-based or hard copy formats acceptable. The online survey design complies 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.

The security of all data collected is 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 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 are 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 are 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 are contacted in person; if they are no longer employed at the study worksite, they are 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) are not allowed to be participants.

**Interventions:** MMH/PH companies have relatively higher rates of cases with days away from work or restricted duty (DAW) involving overexertion, slip/ trip/falls, and struck by objects (BLS 2009). The targeted interventions are not expected to increase risk of injury/illness beyond risks to participants beyond those encountered during their daily work. For example, similar interventions 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 are 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 and patient handling of large loads.

**Questionnaires:** No individuals or participant firms will be identified in published materials. No individuals or participant firms 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 are given a \$5 gas card upon completion of each combined questionnaire data collection (a total of \$45 for the entire study).

## 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**) describe the potential benefits and risks of participation in the study. The grade level for the consent process has been estimated to be the 14<sup>th</sup> 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 are 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 involves 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 is being conducted over six years.

- **Year 1 (2011):** An Information Collection Request (ICR) was submitted to the Office of Management and Budget (OMB). Volunteer OBWC-insured MMH/PH establishments were recruited to participate in onsite MSD intervention studies
- **Year 2 (2012):** Recruitment continued on a rolling basis. The MSD interventions were placed in establishments. Outcome surveys were collected every 3 months from participating employees.
- **Year 3 (2013):** Recruitment continued on a rolling basis. The MSD interventions were placed in establishments. Outcome surveys were collected every 3 months from participating employees.
- **Year 4 (2014):** Recruitment completed for original protocol data collection. The MSD interventions were placed in establishments. Outcome surveys were collected every 3 months from participating employees.
- **Year 4 (2015):** Recruitment will continue on a rolling-basis under new data-collection protocol. The MSD interventions will be placed in establishments. Outcome surveys will be collected every 3 months from participating employees.

- **Year 4 (2016):** Outcome surveys will be collected every 3 months from participating employees. The analysis of study data will be completed to determine the effectiveness of multi-site MSD intervention at OBWC MMH/PH 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 up to a 2 year period. Several methods (described below) are utilized to maximize response rate.

**Online Surveys:** In order to maximize efficiency and reduce burden, a web-based survey is offered for 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 continue to work closely with the OBWC to recruit MMH/PH firms using an informational flyer (**Attachment J-1**). NIOSH works closely with the participating firms to explain the purpose and importance of the study. NIOSH will continue to recruit 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 are asked to provide a contact list for individuals performing delivery operations. NIOSH emails the flyer directly to prospective recruits or call recruits if no email address is available. NIOSH may also visit a sampling of participating firms to meet prospective recruits in person and explain the nature of the study.

**Incentives:** Participants are given a \$5 gas card upon completion of each combined questionnaire data collection (a total of \$45 for the entire study). 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 are 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 is sent. If no response is returned within 3 weeks of the scheduled data collection date, a third email or phone call prompt is sent. If no response is returned within 4 weeks of the scheduled data collection date, a fourth email or phone call prompt is sent to the participant to inquire whether they wish to withdraw from the study. The email and phone script for quarterly prompts is 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

The most likely reason why an individual does 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 expects 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 is 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 is considered that the individual has left the study. For a participant who leaves the study for any reason, an exit interview is used to ascertain whether the reason for leaving was MSD-related health problems (**Attachment H-5**). Replacement participants are recruited from the same establishment if feasible.

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.

#### B14. 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 up to 200 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 is 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). 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 is 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 collects 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 collects covariate exposure information related to overall work conditions, health, and behaviors (28 items, administered to up to 200 participants at baseline and every 12 months for 2 years; 10 minutes estimated time combined per data collection) (**Attachment H-4**). During recent pilot testing at NIOSH, the average time burden for the “Self-reported general work environment and health” form was approximately 10 minutes.

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

NIOSH personnel have primarily designed the data collection, perform the data collection, and analyze the data. Contracted secondary support staff 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)	<a href="mailto:Sw3@cdc.gov">Sw3@cdc.gov</a> 513.841.4322	Project Officer:  Designed data collection, collects and analyzes data
Steve Bertke, Ph.D.	Statistician	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	<a href="mailto:inh4@cdc.gov">inh4@cdc.gov</a> 513.841.4493	Designed data collection and analyzes data
Kaori Fujishiro, Ph.D	Epidemiologist / Statistician	Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)	<a href="mailto:fnd3@cdc.gov">fnd3@cdc.gov</a> 513.841.4120	Designed data collection and analyzes data
Alysha Meyers, Ph.D.	Epidemiologist	Division of Surveillance Hazard	<a href="mailto:itm4@cdc.gov">itm4@cdc.gov</a> 513.841.4208	Collects and analyzes data

		Evaluation and Field Studies (DSHEFS)		
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The Ohio 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	<a href="mailto:Michael.L.1@bwc.state.oh.us">Michael.L.1@bwc.state.oh.us</a> 614.995.1203	Designed data collection
Abe Tarawneh, Ph.D.	Superintendent	Division of Safety and Health	<a href="mailto:Ibraheem.A.1@bwc.state.oh.us">Ibraheem.A.1@bwc.state.oh.us</a> 614.466.0384	Supervising OBWC role on overall project

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Bureau of Labor Statistics. 2009. TABLE R8. Incidence rates<sup>1</sup> for nonfatal occupational injuries and illnesses involving days away from work<sup>2</sup> per 10,000 full-time workers by industry and selected events or exposures leading to injury or illness, 2006.

Bureau of Labor Statistics. 2007. TABLE R8. Incidence rates<sup>1</sup> for nonfatal occupational injuries and illnesses involving days away from work<sup>2</sup> 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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