Supporting Statement A

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

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SECTION A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

Background

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 handling tasks that are expected to be impacted by the engineering control interventions.

NIOSH proposes 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
TOTAL	**103**	**100%**	n/a	**292**	**21**

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.

Original Background for the Study

This original need for this study is expressed in a number of NIOSH Strategic Goals (**Attachment C**). This study will provide current important information on the health and safety of MMH/PH workers that is not available elsewhere. This project is part of the mission of CDC-NIOSH to conduct rigorous scientific intervention effectiveness research to support the evidenced based prevention of occupational injuries and illnesses. Additional information on how this project integrates into CDC's broader research agenda is provided in **Attachment D-1**.

MSDs currently account for approximately 28% of the total non-fatal injuries and illnesses with days away from work or restricted duty (DAW) in private industry (Bureau of Labor Statistics, BLS, 2010). Liberty Mutual has estimated direct workers' compensation costs to industry in the US in 2008 to be $53.4 billion (up from $48.6B in 2006), with $15.2 billion (28%) attributed to MSDs ($13.4B overexertion, $1.8B repetitive motion) (Liberty Mutual 2010 Safety Index). Since the majority of MSDs in MMH/PH are related to overexertion, identifying effective controls to reduce these types of outcomes is an important step to reduce the overall injury/ illness burden.

Studies indicate that overexertion MSDs are primarily caused by physical risk factors associated with MMH/PH, including high task repetition, excessive biomechanical loading on body joints, and awkward body postures (Kumar 2001). It has also been indicated that combined exposure to multiple risk factors (versus single physical risk factors) produce the most adverse health effects (Marras 2000). For example, repetitive and heavy manual lifting in awkward postures have been found to be major risk factors for low back disorders in many studies (Waters et al., 1993; Waters et al., 1998; Marras et al., 1995; Westgaard et al., 1996; NIOSH 1997; Gagono et al., 2000). Although it is proposed that primary prevention interventions designed to reduce the multiple risk factors involved in MMH/PH (high force, awkward postures, task repetition) will reduce future overexertion MSDs, relatively few true experimental studies have been conducted to test this hypothesis. Most MSD intervention effectiveness studies have been quasi-experimental (e.g. pre- and post- intervention studies without control groups or randomization). Those studies that have focused on the effectiveness of MSD

engineering controls alone have tended to focus on short term workload assessments as outcomes rather than MSD symptoms/ cases and have been mixed in quality and findings (van der Molen et al 2005). For example, several recent literature reviews (Bigos et al. 2009; van Duijvenbode et al 2009; Sahar et al 2009; Tveito et al 2004) found few high-quality studies to support the efficacy of engineering ergonomic interventions designed to reduce low back pain. See **Attachment D-2** for additional information on prior MSD intervention studies.

Clearly there is a need to conduct rigorous experimental and quasi-experimental research to define further the effectiveness of MSD control interventions. A renewed partnership between NIOSH and the Ohio Bureau of Workers Compensation (OBWC) provides a timely opportunity to conduct such research in a relevant, efficient, and impactful manner. Although several researchers have published studies using OBWC data in the past, OBWC and NIOSH have developed a formal agreement (**Attachment E-1**) to collaborate on a number of research goals, including descriptive WC data analyses, evaluation of prior OBWC-sponsored programs, and prospective intervention research. OBWC has many strengths as a potential research partner, including its size (approximately 250,000 insured establishments), diversity of industry that is largely representative of the larger US in both industry classification [both general 2-digit North American Industry Classification System (NAICS)] and establishment size distribution (**Attachment E-3**), geographical proximity to the Cincinnati, OH and Morgantown, WV locations of NIOSH, and perhaps most importantly, their active engagement in intervention research. OBWC represents an ideal translational research partner. OBWC is an extremely pro-active workers compensation insurance carrier that spends millions of dollars annually supporting many programs to encourage insured companies to improve their primary through tertiary OSH prevention programs. For example, in 1999 OBWC initiated a program known as “Safety Grants” to provide matching funds to insured employers to put into place OSH controls and measure effectiveness. From 1999 to 2009, this was a 3-1 (OBWC to employer) matching with up to $40,000 per grant. Over the history of the program, OBWC has provided over 1,500 Safety Grants, with approximately 100 grants implemented per year and a total of $3 million annually in matching funds. As with all OBWC programs, insured companies are encouraged to participate and submit grant applications. Initial ideas for feasible controls often originate during field consultation visits by OBWC loss control staff (safety, ergonomics, and industrial hygiene specialists) while working directly with the personnel of insured companies. Occasionally, OBWC targets specific industries with interventions. For example, OBWC targeted nursing homes because of high MSD rates and the presence of feasible control options (patient handling devices and practices). To receive the grant, OBWC requires that companies participate in onsite evaluations to document before and after workplace changes and provide 2 years of follow-up data. A number of completed Safety Grant projects (~15%) are shared as “best practices” for various sectors through the OBWC website.

In summary, OBWC has years of experience in developing, implementing, evaluating, and disseminating OSH controls with clients and has in effect conducted 1,500 quasi experimental intervention studies. Although OBWC has actively engaged in prevention

research, the organization is dedicated to demonstrating the effectiveness of their various programs using the most scientifically rigorous methods possible. For this reason, OBWC is eager to collaborate with NIOSH on a number of research projects including this MSD intervention research study. In this way, evidence based practices can be shared with the greatest audience possible and OBWC can efficiently allocate their own resources among program alternatives that range widely from primary prevention to disability management.

Privacy Impact Assessment

The study has been collecting both potentially sensitive data (self-reported MSD symptoms and results from low back functional assessments) and personal identifiers (name, address, phone number, employee clock number). 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. All data collection and records management practices and systems (including the online survey) 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 is being stored on encrypted CDs, flash drives, and/or secure file transfer protocol (sftp) sites according to applicable Federal Information Processing Standards Publications (FIPS PUBS, see http://www.itl.nist.gov/fipspubs). See the Information Security Plan in **Attachment F** for more information.

Questionnaires are being administered using paper surveys and a self-administered secure web portal. The survey is on a secure web site that is accessible by sampled members of the participating establishments. The hyperlink and internet address to the survey is only made available to members of participating establishments and researchers conducting the study. The information will not be directed at children under the age of thirteen years. Aggregated survey results will be made available on the NIOSH public internet site. Please see below for additional information related to the Privacy Impact Assessment.

Overview of the Data Collection System

Questionnaires are being administered using several options (self-administered secure web portal, self-administered hard copy forms, and telephonic interviews). The respondent is 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 be 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. Survey data collected for this study using an online secure website complies

with applicable 508 requirements to accommodate individuals with disabilities (http://www.hhs.gov/od/508policy). NIOSH researchers are primarily conducting the data collection and contractors are being used in support roles for data management. Information will be maintained until the conclusion of the study in 2016.

Items of Information to be Collected

Information in identifiable form (IIF) is being collected as part of the informed consent form (**Attachments G-1)** for this study. This includes: first and last name, street address, phone number, email address, and date of birth.

Additional information collected is described below. All information will be used to determine whether there are significant differences in reported musculoskeletal pain and functional back pain score ratios (pre/ post intervention scores) when intervention and control groups are compared, while controlling for covariates. Individual participant personal information will not be published in any identifiable form and is protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). The questionnaires are standard tools used to establish the degree of clinical disorder (lumbago) and upper extremity pain among the participants. The study is designed to determine the usefulness of the prophylactic intervention in preventing lumbago and upper extremity pain.

1: 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; 5 minutes estimated time combined per data collection **Attachment H-1**).

- 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; 5 minutes estimated time combined per data collection **Attachment H-2**).

- Self-reported specific job tasks and safety incidents: This questionnaire collects exposure information regarding specific tasks related to the use of the intervention, material handling exposures, and safety incidents (20 items; 5 minutes estimated time combined per data collection **Attachment H-3**).

2: 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).**

A limited amount of digital video may be collected at participant sites to document the types of tasks being conducted pre- and post-intervention. Several additional onsite task analyses may also conducted pre- and post-intervention to assess the biomechanical and physiological work demands. These 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 of 1974, Title 5, United States Code, Section 522 (a). 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 asked for permission to video, and uses of participants' video data will be explained to them (**Attachment G-3**). 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.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

As described, the proposed continued research involves the collection of information through a secure website and paper surveys. The research does not direct any website content at children under 13 years of age. All data collection and records management practices and systems (including the online survey system) 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]. See the Information Security Plan in **Attachment F** for more information.

A2. Purpose and Use of Information Collection

All information collected will be used to determine whether the tested MSD interventions are effective in reducing self-reported back and upper extremity pain among MMH/PH personnel. 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). The privacy of all data collected is being protected to the extent legally possible, as covered by the Privacy Act of 1974, Title 5, United States Code, Section 522 (a). Individual participant personal information will not be published in any identifiable form.

The data collection for the MSD intervention study is part of a multi-phase project between NIOSH and OBWC that is fully funded from Fiscal Year 2011 through Fiscal Year 2016. The project was awarded federal funds through the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. OBWC is also funding the majority of costs of the actual interventions (powered hand trucks and lift gates) through a 3:1 matching grant process.

The data collection is justified because very few trials for the effectiveness of MSD controls have been conducted for both reported symptom and injury/illness outcome. Clearly there is a need to conduct rigorous research to define further the effectiveness of MSD control interventions. This will enable evidence based practices to be shared with the greatest audience possible. Such data has practical utility to the federal government, state government, and private stakeholders.

State organizations such as the OBWC that sponsor prevention programs are seeking to evaluate the effectiveness of their various programs using the most scientifically rigorous methods possible. For this reason, OBWC is eager to continue to collaborate with NIOSH on this project and OBWC continues to offer substantial financial resources (over $15 million in matching grants) to support the general intervention program. The goal is to identify evidence based practices and programs can be shared with the greatest audience possible. In this way, OBWC can efficiently allocate their resources among program alternatives that range widely from primary prevention to disability management. OBWC and NIOSH have also formalized an agreement (**Attachment E-1**) to outline a collaborative research partnership and specify a data sharing agreement to ensure data security. This expanded MSD intervention study represents another step towards addressing many of the partnership goals and OBWC is committed to supporting these projects (see the letter of support from OBWC in **Attachment E-2**).

The results of the current study are also relevant for private companies (such as MMH/PH companies, workers compensation or health insurance carriers) that may sponsor prevention programs. Sponsored-grant programs for engineering controls (like the OBWC Safety Grants program involved in this study) are currently rare among private insurance companies. If a rigorous study can determine the level of effectiveness of such a program, other insurance and MMH/PH companies may utilize this data to determine whether such a program should be implemented or expanded.

The findings from this project will also be transferred to private stakeholders and OSH practitioners using several main channels:

OBWC (website, publications, annual safety conference, and personnel)

- The OBWC has a developed infrastructure to reach companies within the state of Ohio. NIOSH and OBWC just signed a formal agreement and this project will leverage this collaboration to encourage participation in the studies, solicit input from MMH/PH companies, and provide results as they become available. As well, OBWC offers a free yearly safety conference (with an

average attendance of ~6,000) where presentations and workshops about the studies will be conducted.

NIOSH (website, publications, and personnel)

- Links to the same dissemination products outlined in the OBWC section above will also be cross promoted on the NIOSH website.

MMH/PH trade organizations (website, publications, and personnel)

- Links to the same dissemination products will also be provided directly to several trade organizations (such as the Retail Industry Leaders Association). Additional outreach is already being conducted with other MMH/PH trade organizations within the state of Ohio to raise awareness of NIOSH in general, and the specific studies with OBWC and to solicit input and participation in the research. Aspects of the studies will also be submitted for publication in trade journals.

Peer reviewed journals

- For this study, at least one manuscript will be submitted for publication in a peer reviewed journal. Main audiences for these types of journals are fellow researchers, but also OSH practitioners.

Privacy Impact Assessment Information

Information in identifiable form (IIF) is being collected as part of the informed consent form (**Attachment G-1)** for this study. This includes: first and last name, street address, phone number, email address, and date of birth. Individual information is not be collected on the other surveys, which are identified only using unique identifier (created by NIOSH) to track the responses of the participant over the course of the study. Individual participant personal information are not be published in any identifiable form and are protected to the extent allowed by law (Freedom of Information Act and the Privacy Act). Information will be maintained until the conclusion of the study in 2017. The IIF data will only be used by NIOSH researchers for the purposes outlined below.

IIF Being Collected	**Purposes**
First and last name of individual participant	The participant's first and last name (in combination with their birth date) is used to link to a unique identifier (created by NIOSH) to track the responses of the participant over the course of the study.
Street address of individual participant	The street address is used to send the participant hard copy questionnaires if the participant requests paper versions for their mode of data collection. The street address is used to send a hard copy of final study results if requested by the

	individual.
Phone number of individual participant	The phone number is used if the participant requests a phone interview for their mode of data collection. If the participant gives permission, the phone number is used to prompt participants to submit quarterly data collections. If the participant gives permission, the phone number is used for the early exit interview to contact those participants who choose to leave the study.
Email address of individual participant	If the participant gives permission, the email address is used to prompt participants to submit quarterly data collections.
Date of birth	The participant's date of birth (in combination with their first and last name) is used to link to a unique identifier (created by NIOSH) to track the responses of the participant over the course of the study. The date of birth is compared to a self-reported "age in years" that is used as a covariate in analyses.

The proposed survey contains one question that may be considered sensitive as it is related to sexual behavior (item 13 in the standard NASS Lumbar Spine Outcome Assessment Instrument, **Attachment H-1**). The question is not explicit (described in A11 below) only inquires about sexual behavior for the purposes of establishing the level of back pain. The impact on the privacy of the individual is considered to be minimal if there were a breach of security.

A3. Use of Improved Information Technology and Burden Reduction

In order to maximize efficiency and reduce burden, a web-based survey is an option for all data collections. At a secure web site, the survey is constructed for easy respondent use, allowing the automatic administration of skip patterns, while maintaining a simple, seamless navigation. Web-based surveys have gained increasing acceptance as a research tool as they offer many advantages, including:

- On-line surveys create cost efficiencies because respondents complete them during a much shorter window of time than other survey modes, and at a substantially reduced cost (i.e., less labor is involved than telephone or in-person surveys; postage is required for mail-based surveys);

- 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);

- All responses are automatically recorded, allowing for minimal data cleaning, and

rapid tabulation and analysis of findings;

- 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.

The respondent is 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. It is estimated approximately less than 1% of respondents require personal interview formats.

A4. Efforts to Identify Duplication and Use of Similar Information

NIOSH has searched the scientific literature, contacted colleagues at NIOSH and OSHA, contacted professional, labor and industry organizations representing MMH/PH workers. To date, NIOSH is unaware of any prospective MSD intervention effectiveness study being conducted involving MMH/PH operations with such a prospective design as the current study.

A5. Impact on Small Businesses or Other Small Entities

Small OBWC-insured businesses that perform material-handling operations are included in this study. To reduce burden for all respondents, a web-based survey is offered for the data collection. All participants are asked to complete the entire survey, but questions have been held to the minimum required for the intended use of the data.

A6. Consequences of Information Collected Less Frequently

Respondents are asked to respond to the data collection at baseline and every 3 months for a 2 year period. The data being collected includes self-reported low back/ upper extremity pain, material handling exposures and usage of the MSD intervention (**Attachments H1- H4**). The frequency of this data collection is justified because musculoskeletal pain and exposures can vary over time (McGorry et al 2011) and less frequent measures would not be sensitive to episodes of pain that resolve within a 3 month period or to changing work exposures. The frequency of data collection is already at a minimum level to reduce burden on respondents while also retaining sensitivity for a valid intervention effectiveness study. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection activity. This request fully complies with regulation 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A: In accordance with 5 CFR 1320.8(d), a review of the proposed study was sought through a 60-day publication period in the *Federal Register* (June 4, 2014, Vol. 79, No. 107, pages 32299 - 32300), (**Attachment B**). No comments were received in response to the Federal Register notice.

B: NIOSH has consulted with numerous individuals and organizations outside the agency regarding the availability and usefulness of the proposed data collection. The following chronology documents these contacts:

2009

NIOSH researchers met several times with OBWC representatives from 2009-2010 to establish a long term and sustainable research partnership and discuss research goals and projects. A formal agreement (**Attachment E-1**) was then developed outline a collaborative research partnership and specify a data sharing agreement to ensure data security. An early stated goal was to evaluate the effectiveness of the OBWC sponsored prevention programs such as the Safety Grants program described earlier. NIOSH and OBWC co-developed the current MSD research study as a way to determine if the grants were functioning to reduce MSD symptoms in target employees. As indicated in the background literature review, very few MSD intervention studies have been designed in such a rigorous way and conducted for this purpose.

January 2010

During the development phase of this project, NIOSH conferred with other researchers from the Institutes for Work and Health (Dr. Ben Amick) about the design of the MSD intervention study.

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Department of Health Policy and Management Robert Stempel College of Public Health & Social Work
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March to July 2010

The MSD intervention study was peer-reviewed as part of a multi-phase project between NIOSH and OBWC and rated based on project approach, potential impact, innovation, and significance through the NIOSH National Occupational Research Agenda (NORA) competitive process for intramural research. The project received favorable scores and was chosen for funding by NIOSH from Fiscal Year 2011 through Fiscal Year 2014. The OBWC is also funding the majority of costs of the actual MSD interventions (powered hand trucks and lift gates) through a 2:1 matching grant process. The review panel for the NORA Fiscal Year 2011 process is listed below.

2011 NIOSH NORA Peer Review **Intervention/Measurement/Training/Evaluation**		
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December 9, 2010

NIOSH and OBWC presented an overview of the study to the NIOSH MSD NORA Cross-Sector meeting. This meeting includes MSD researchers from across NIOSH and academic institutions. The MSD intervention study was discussed informally during the meeting and feedback was received.

January 2011

NIOSH continued to work with OBWC to refine the MSD intervention protocol. As part of this process, NIOSH solicited input from OBWC staff ergonomists to determine what ergonomic engineering controls (equipment, tools, work station designs) they have recommended for MMH clients, which controls have been most effective in reducing MSDs, and what controls need to be developed for MMH. This information was used to develop background information for the focus meeting described next. Those contacted are listed below.

Steve Hanna, Ergonomist, OBWC, 330-904-4315, Stephen.h.1@bwc.state.oh.us
Dennis Apple, Ergonomist, OBWC, 740-435-4333, Dennis.apple@bwc.state.oh.us
Mike Rienerth, Ergonomist, OBWC, 216-538-9724, Michael.R.1@bwc.state.oh.us

January 24, 2011

NIOSH held a focus group meeting at NIOSH in Cincinnati, OH with 8 OBWC staff to discuss additional interventions and target industries to add to the MSD intervention study to meet OBWC's needs further and broaden study reach. OBWC Attendees included:

Cheryl Giordano, Ergonomist, 513-520-7071, Cheryl.G.12@bwc.state.oh.us
Mark Giordano, Ergonomist, 513-520-2618, Mark.G.1@bwc.state.oh.us

Trish Harris, Service Office Manager, 513-583-4512, Patricia.H.1@bwc.state.oh.us
Mike Lampl, Ergonomics Technical Advisor, 614-995-203, Michael.L.1@bwc.state.oh.us
Carol Morrison, Manager, Business Development, 614-644-8225, Carol.M.1@bwc.state.oh.us
Theresa Paxton, Ergonomist, 513-520-8167, Theresa.P.1@bwc.state.oh.us
Mireya Springer, Ergonomist, 614-562-5417, Mireya.S.1@bwc.state.oh.us
Ivana Wireman, Ergonomist, 937-269-6040, Ivana.W.1@bwc.state.oh.us

As a summary, the group agreed that the best way to expand the study would be to keep the focus on the material handling of large items (100+ lbs.) or stacked smaller items (1-100 lbs. per item, 100+ lbs. per stack), mainly during delivery-related operations, but include a wider variety of MMH companies (appliance/ furniture delivery; beverage distribution; food distribution; heating/ ventilation suppliers; vending services; and office supplies- copier service). The group also agreed that the study should focus on two priority controls (powered hand trucks and lift gates). The group further agreed that the expanded MMH study will meet many of the needs for ergonomic research in the transportation sector because the focus will be mainly on delivery operations with similar risks. Next steps were outlined to:

- Find current and potential users of priority controls among OBWC MMH clients
- Seek input from MMH clients about ergonomic best practices through Safety Council meetings and onsite visits to build case study library
- Facilitate NIOSH visits to OBWC MMH clients (especially current users of controls)
- Begin informal recruiting of new clients for study
- Prepare a new Safety Grants application for MMH study for formal recruiting

February to March 2011

NIOSH and OBWC contacted several OBWC MMH clients who were current users of the intended controls. Feedback via emails and phone calls was received about the effectiveness of the control and the general design of the new study. Those contacted are listed below.

Roger Patten, r.patten@frontier.com
Ken Norris, knorris6@columbus.rr.com
Rick Stephenson, r.stephenson@zoominternet.net

NIOSH and OBWC also contacted trade associations (Ohio Association of Wholesaler – Distributors, Ohio Council of Retail Merchants, Ohio Wholesale Marketers Association, Wholesale Beer & Wine of Ohio) to advertise the study and solicit feedback . Those contacted are listed below.

Trade Organization	Contact	Contact Phone	Contact Email
Ohio Association of Wholesaler - Distributors	Ed Cain	614.221.7833	edwardc@ohioretailmerchants.com
Ohio Council of Retail Merchants	Gordon Gough	614.221.7833	gordong@ohioretailmerchants.com
Ohio Wholesale Marketers Association	Beth A. Wymer	614.224.3435	owma@att.net
National Retail Hardware Association	Thomas Smith	317.275.9432	tsmith@nrha.org
Wholesale Beer & Wine of Ohio	Susan Remy	614.224.3500	sremy@wbwao.org

March 15, 2011

NIOSH sponsored a meeting in Cincinnati on March 15, 2011 to discuss the overall NIOSH and OBWC research collaboration. The MSD intervention study was discussed informally during the meeting and feedback was received.

March 31, 2011

NIOSH gave a session presentation on March 31, 2011 at the Ohio Safety Congress (an annual conference sponsored by OBWC that averages over 6,000 attendees) to detail current research including the current MSD intervention study. Informal feedback was solicited about the study among OBWC-insured MMH clients and OBWC staff. The study was also highlighted during the one of the conference's keynote addresses. An informational flyer about the study (**Attachment J-1**) was also disseminated at the conference.

April 2011

NIOSH and OBWC sent the informational flyer (**Attachment J-1**) to all OBWC safety and health staff, and to all OBWC-sponsored Safety Councils. The safety councils include over 20 regional groups throughout Ohio that are composed of diverse group of members including labor organization representatives, trade association members, and OBWC-insured company safety and health staff. The purpose of the Councils is to provide a forum for sharing best safety/ health practices among members through regular meetings and events. The councils were informed about the study and asked for feedback.

May 2014

OBWC expanded the Safety Intervention Grant program, quadrupling the annual budget. OBWC also released restrictions on many types of material handling 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 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.

A9. Explanation of Any Payment or Gift to Respondents

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.

A10. Assurance of Confidentiality Provided to Respondents

The interview collects potentially sensitive information about health status. Risks to participants are low since the only information in identifiable form (IIF) is being collected for the purposes of informed consent. Each participant that enrolls in the study is subsequently identified only with a code on all other information collection forms. IRB approval for this data collection has been obtained (**Attachment K**).

Several controls (safeguards) have been put into place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected. Records are retained and destroyed in accordance with the applicable CDC Records Control Schedule (see http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy449.htm**)**. Controls are summarized in the table below.

Control Descriptions	Control Type
• User Identification • Passwords • Firewall • Virtual Private Network (VPN) • Encryption • Intrusion Detection System (IDS) • Common Access Cards (CAC) • Smart Cards	Technical
• Guards • Identification Badges • Key Cards	Physical

• Closed Circuit TV (CCTV)	
1. **Security Plan:** The system security plan for this information collection is detailed in **Attachment F.** 2. **Contingency Plan:** Files are backed-up weekly using an offsite Microsoft SQL server based in Atlanta, GA CDC offices. 3: **User Manuals**: Created for this information collection. 4. **Personnel Training**: All CDC and contract personnel (principal investigator, managers, operators, contractors and/or program staff) receive yearly training using the system and made aware of their responsibilities for protecting the information being collected and maintained. 5. **Contractor Adherence**: Contracts for staff that operate or use the system include clauses ensuring adherence to privacy provisions and practices. 6. **Access Levels**: Methods are put into place to ensure the least privilege possible (e.g., access is "role based" on a "need to know" basis). Accountability is ensured through yearly security reviews. 7. **IIF Policy**: There are CDC policies or guidelines in place with regard to the retention and destruction of IIF.	Administrative

Privacy Impact Assessment Information

A. The CDC's Information Collection Review Office has reviewed this application and has determined that the Privacy Act is applicable.

B. Access to individual data has been limited to authorized NIOSH researchers and contractors. Physical controls: NIOSH facilities have 24-hour security guards, and key card ID badges must be used to enter the buildings. Data in hardcopy form is being stored in locked rooms or cabinets. Technical controls: all electronic data is stored on secure servers that are protected with firewalls and passwords. Any contractor charged with data collection, preparation, or management tasks to be performed away from a NIOSH facility is required to follow equivalent procedures.

The process for handling security incidents is defined in the system's Information Security Plan (**Attachment F**). Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security

Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate

C. Respondents are asked to sign a written consent form (**Attachment G-1)**. The form describes how respondents are informed about the intended uses of the information collection and plans for sharing the information.

D. Respondents are informed that their participation is voluntary, and that they may discontinue the survey at any time. They are advised that they will not lose any benefits to which they are otherwise entitled if they chose not to participate. The Privacy Act does apply and the informed consent form (**Attachments G-1**) addresses the effect on the respondent of not responding to the data collection request, the intended uses of the data, with whom information will be shared, and the legal authority for the data collection.

A11. Justification for Sensitive Questions

The proposed survey contains one question (included in the standard NASS Lumbar Spine Outcome Assessment Instrument, **Attachment H-1**) related to sexual behavior that may be considered sensitive. This question is provided below:

13. In the past week, how has pain affected your sex life?

My sex life is unchanged.
My sex life is unchanged, but causes some pain.
My sex life is nearly unchanged, but it is very painful.
My sex life is severely restricted by pain.
My sex life is nearly absent because of pain.
Pain prevents any sex life at all.

The question is not explicit and only inquires about sexual behavior for the purposes of establishing the level of back pain. This question is part of the NASS 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). To remove this question may negatively affect the scoring of the questionnaire and comparisons to numerous other studies that have used the questionnaire with this particular question. Answering these questions poses little risk to the driver since all NASS questionnaires are coded with a participant ID and only linked to data of individually identifiable form (IIF) that is being collected for the informed consent process.

A12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden to Respondents

No direct costs accrue to respondents other than their time to complete the survey. We estimate that a maximum of 200 individuals will participant in the MSD intervention data collection. This includes up to 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 of large items. The hour-burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All hour-burden estimates were derived based on estimates reported in the literature for these instruments, from prior CDC-NIOSH studies that utilized these forms, and informal pilot testing. No new formal samples of respondents were performed. The number of early exit interviews is based on an estimated 11% exit rate.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Manual material handling workers *(Completion Of Original Data Collection)*	Self-reported low back pain	87	3.5	5/60	25.4
	Self-reported upper extremity pain	87	3.5	5/60	25.4
	Self-reported specific job tasks and safety incidents	87	3.5	5/60	25.4
	Self-reported general work environment and health	87	1.5	10/60	21.8
	Early Exit Interview	5	0.5	5/60	0.2
	Sub-Total to Complete Original Data Collection				*98.2*
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)

Manual material and patient handling workers *(Completion of Additional Revised Data Collection)*	Self-reported low back pain	200	4.5	5/60	75
	Self-reported upper extremity pain	200	4.5	5/60	75
	Self-reported specific job tasks and safety incidents	200	4.5	5/60	75
	Self-reported general work environment and health	200	1.5	10/60	50
	Informed Consent Form (Overall Study)	200	.5	5/60	8.3
	Early Exit Interview	10	.5	5/60	0.4
Sub-Total to Complete Additional Revised Data Collection					*283.7*
Grand Total for Original and Revised Data Collection					***382***

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden (in hours)	Average Hourly Wage Rate	Total Respondent Costs
Manual material handling workers *(Completion Of Original Data Collection)*	Self-reported low back pain	25.4	$16.28	$414
	Self-reported upper extremity pain	25.4	$16.28	$414
	Self-reported specific job tasks and safety incidents	25.4	$16.28	$414
	Self-reported general work environment and health	21.8	$16.28	$355
	Early Exit Interview	0.2	$16.28	$3
	Sub Total to Complete Original Data Collection			*$1,599*
Type of Respondent	Form Name	Total Burden (in hours)	Average Hourly Wage Rate	Total Respondent Costs
Manual material and patient handling workers	Self-reported low back pain	75	$16.28	$1,221
	Self-reported upper extremity pain	75	$16.28	$1,221

(Completion of Additional Revised Data Collection)	Self-reported specific job tasks and safety incidents	75	$16.28	$1,221
	Self-reported general work environment and health	50	$16.28	$814
	Informed Consent Form (Overall Study)	8	$16.28	$130
	Early Exit Interview	0.4	$16.28	$7
	Sub-Total to Complete Additional Revised Data Collection			*$4,614*
	Grand Total for Original and Revised Data Collection			*$6,213*

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to respondents.

A14. Annualized Cost to the Government

Total costs include work performed over the course of four years by CDC research personnel (1 industrial hygienist, 2 epidemiologists, and 1 statistician) and contracted administrative personnel, including tasks such as: (1) development of survey materials; (2) development of sampling frame and sample selection; (3) survey conduct; (4) sample tracking; (5) data receipt and processing; and (6) data entry and delivery. Estimated annualized costs to the Federal Government for the survey period are presented in Table A.14-1 below.

Table A.14-1. Estimated Annualized Cost to the Federal Government

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	TOTAL PROJECT	Annualized Cost
CDC Personnel Salaries and Benefits [a]	$16,589	$17,418	$18,288	$19,203	$20,163	$21,171	$112,832	$18,805.33
Contracts	$13,000	$13,000	$0	$0	$0	$0	$26,000	$4,333.33
Travel	$500	$500	$500	$500	$0	$0	$2,000	$333.33
Supplies	$0	$500	$500	$500	$500	$500	$2,500	$416.67
OTHER (Incentives for participants to complete surveys)	$0	$250	$1255	$2105	$2105	$1255	$6,970	$1,162
						TOTAL	$150,302	$25,050

The annualized cost to the Federal Government is $25,050.

A15. Explanation for Program Changes or Adjustments

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.

• 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.

• 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.

A16. Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis of the Data

Data collection will be completed in FY16, followed by statistical analysis and dissemination of data. A full description of the statistical protocol is provided in Part B1 and B2 of this ICR. Results will be made available through publication in scientific journals and notices in trade publications, and through digital media such as the Internet.

Project Time Schedule

- **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.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for an expiration date display exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions being sought to the certification statement.